Supreme Court, U.S.
FILED

(1) 932052 JUN 9 1994

OFFICE OF THE CLERK

No.

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1993

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

ROBERT J. DEBRY
Counsel of Record
ROBERT J. DEBRY & ASSOCIATES
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

102 pp

QUESTIONS PRESENTED

1. Is the Nuremberg Code part of due process constitutional law or federal common law?

2. Does a United States district court have a mandatory duty to provide notice and a meaningful hearing before denying a motion to certify a class action when, as in this case: a) all F.R.C.P. 23 requirements are apparently met; b) the court denies class action certification on a ground not specified in F.R.C.P. 23; and c) the proposed class representatives have no opportunity to address the reason identified by the district court for its decision denying class certification?

3. May mandamus be used to review and correct a defective class certification proceeding?

4. Does the district court have a mandatory duty to make and enter meaningful findings in support of its ruling denying class action certification?

LIST OF PARTIES AND RULE 29.1 STATEMENT

The parties to the proceedings below were the following petitioners:

Connie Albrecht;
Bonita Allgood;
Dorothy Anderson;
Claudia Archuleta;
Lynn Atherley;
Tamera Baker;
Mary Jane Balok;
Sally Barela;
Kathy Barnes;
Corrinne B; Beach;
Piper Beagley;
Linda Beaucannon;
Merlene Beheshti;
Barbara Bluemel;
Michelle Braithwaite;
Vera Burton;
Debra Cannon;
Carol Card;

Leslie Cheesman;
Raelynn Christensen;
Janice Connelly;
Shirlyn Cornwell;
Georgia Cragun;
Charlotte Crawford;
Roberta Crosgrove;
Mary Crozier;
Ann Cummins;
Jan Curnutt;
Julie Datwyler;
Judy Davison;
Jean Dickson;
Jane Does 1-12, 14-17;
Mae Dumas;
Carol Dunton;
Teresa Eastmond;
Sharon Ficklin;
Kathy Frazier;
Janet Gates;
Pat Gehring;
Peggy Genebach;
Sylvia Hansen;
Connie Hardcastle;
Sondra Harris;
Kerry Hill;
Jannette Hooley;
Mary Hualde;
Laraine Hunter;
Louise Hunter;
Sharon Jensen;
Jeri Johnson;
Maria Johnson;
Renae Johnson;
Lauri Jones;
Leda Jones;
Diann Joseph;
Connie Kaleel;
Carol Kendrick;
Julie Ketterer;
Ruth Leonard;
Dawn Lether;
Jenn Leydsman;
Candace Lish;
Kathy Litson;
Sandra D; Lund;
Rafaelita Martinez;
Annalee McGugin;
Ooma Menlove;
Teresa Mickelsen;
Kathy Nelson;
Sharon Nichols;
Sondra Nielsen;
Janice Oltersdorf;
Vicki Owens;
Kathy Peck;
Peggy Pendleton;
Kris Peterson;
Julie Pettersson;
Barbara J. Pledger;
Virginia Plowman;
Madalyn Ramos;
Sherion Reay;
Cindy Reimann;
Nedra Riley;
Brenda Riney;
Debra Robb;
Beckie Sanchez;
Liz Savage;
Brenda Scott;
Concilia Sipe;
Lavena Smith;
Janet Stewart;
Valois Strait;
Shirley Streeter;
Suzanne Stubbs;
Lisa Sutherland;
Helen Sweeney;

Dixie Taylor;
Tresa Taylor;
Trena Terry;
Carolyn Thompson;
Barbara Timmons;
Geraldine Vybiral;
Carol J. Waddoups;
Jana Wahler;
Pam Walker;
Michelle Weakland;
Lisa Westbury;
Janice White;
Agaytha Willis; and

the respondent is the United States District Court for the Northern District of Alabama, the Honorable Samuel C. Pointer, Jr. presiding.

Parent and subsidiary corporations in the underlying litigation are disclosed under Rule 29.1 of the Supreme Court of the United States as follows:

Dow Corning Corp.
Surgitek, Inc.
Medical Engineering Corp.
Bristol-Myers Squibb Co.
McGhan Medical Corp.
Inamed Corporation
Mentor Corporation
Heyer Schulte Corporation
American Hospital Supply
Baxter Healthcare Corp.
Baxter International, Inc.
Bioplasty, Inc.
Biomanufacturing, Inc.
CUI Corporation
Cox-Uphoff Corporation
Replicon Laboratories, Inc.
Natural Y Surgical Specialties, Inc.
Aesthetech Corporation
Cooper Companies
"21" International Holdings, Inc.
Wilshire Foam Products, Inc.
Sirod Corporation

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

To the Honorable Chief Justice and Associate Justices of the Supreme Court of the United States.

Connie Albrecht, et al., the petitioners herein, pray that a writ of certiorari issue to review an Order entered on March 11, 1994 by the United States Court of Appeals for the Eleventh Circuit in the above entitled case. The Order denied a petition for mandamus to compel the Honorable Samuel C. Pointer, Jr., presiding judge of the United States District Court for the Northern District of Alabama, to hold a hearing on petitioners' motion to certify the

class of women who received silicone breast implants in violation of the Nuremberg Code, and failed to enter meaningful findings supporting its class certification decision.

OPINION BELOW

The order of the United States Court of Appeals for the Eleventh Circuit is printed in the Appendix, p. A-1, infra. The Order(s) of the United States District Court for the Northern District of Alabama denying class action certification are in the Appendix, pp. A-10, 11 infra. None of the opinions or orders are reported.

JURISDICTION

The jurisdiction of the United States is invoked under 28 U.S.C. § 1254 (1). The order of the United States Court of Appeals, which denied the petitioners' writ of mandamus to compel the lower court to hold a hearing on their motion to certify the class and to enter meaningful findings, was entered on March 11, 1994.

CONSTITUTIONAL PROVISIONS, RULES AND STATUTES INVOLVED

The constitutional provisions, rules and the statutes involved in this proceeding are:

U.S. Const. amend. V; Federal Rules of Civil Procedure, 23; Federal Rules of Civil Procedure, 52; Nuremberg Code.

Copies are set forth in the Appendix, p. A-2-9, infra.

STATEMENT OF THE CASE

The petitioners are 123 women who each received silicone breast implants. The defendants are implant manufacturers. The petitioners filed their class action lawsuit in the United States District Court for the District of Utah. The action is titled Albrecht, et al. v. McGhan Medical Corp, et al., Case No. 92-C-0889J (October 14, 1992). Jurisdiction was invoked under 28 U.S.C. § 1332. The lawsuit is hereinafter sometimes referred to as "the Utah class action."

Before a hearing could be held on a motion to certify the class, the Utah class action was transferred pursuant to 28 U.S.C. § 1407 with other implant litigation to the United States District Court for the Northern District of Alabama, Northern Division. The Honorable Samuel C. Pointer, Jr. presides over the transferred litigation.

The Utah class action complaint pleads a distinct cause of action not found in any other breast implant litigation: a claim for unlawful human experimentation. The legal foundation for the unique Utah claim is the Nuremberg Code. (Appendix, p. A-23-27, infra.) The Nuremberg Code war trials declared basic ethical standards for all human experimentation. See United States v. Stanley, 483 U.S. 669, 687 (1987) (J. Brennan, concurring and dissenting).

The Nuremberg Code, inter alia, explicitly provides:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him

> to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> (3) The experiment should be so designed and based on the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

(Nuremberg Code at paragraphs 1 and 3.) The Nuremberg Code also provides:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.) These basic principles underlie modern tort theory and subsequent ethical pronouncements on human experimentation.

The petitioners' complaint alleges that the breast implant manufacturers did not conduct adequate animal tests or reveal then known risks to the implant recipients. (Appendix p. A-23-27, infra.) Thus, the women are ipso facto subjects of mass human experimentation in violation of the Code principles.

Under the Nuremberg Code, the women do not have to show causation or injury. Moreover, under the Nuremberg Code theory,

the petitioners seek a mandatory affirmative injunction requiring the manufacturers to inform all breast implant recipients of the known risks and side effects. Being fully informed would confer on each petitioner a meaningful opportunity to bring the experiment to an end by removal of the implants and breast reconstruction at the manufacturer's expense.

After commencing the implant litigation, Judge Pointer requested the litigants to identify pending motions. In response, the petitioners notified the Court that there was a pending motion to certify the Utah lawsuit as a class action. The petitioners requested a hearing. (Appendix, p. A-15-16 infra.) However, Judge Pointer did not hold a hearing. Instead, without notice, and in a conference with other counsel, the Court made the following bench ruling:

THE COURT: The very first one, Albrecht v. McGhan, motion for class certification 92-11104. There's an effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor.

THE COURT: Before you say anything, I am going to deny the motion for class certification.

(Laughter)

Transcript of Proceedings of January 2, 1993, p. 161, lns. 17-25.[1]

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[1] A copy of the transcript is attached in Appendix, p. A-12-14, infra.

Unaware that the Court had ruled, petitioners' counsel again requested a hearing (Appendix, p. A-17-22 infra.) Without a hearing, the Court responded with a one-sentence order denying certification. (Appendix, p. A-11, infra.)

Because of the perfunctory nature of the Order, the petitioners filed a Motion that Findings of Fact and Conclusions of Law be Entered. Again, no hearing was held, but the Court entered another order:

> Plaintiff's motion that findings of fact and conclusions of law be entered is hereby granted. The court concludes that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED.

(Order entered July 12, 1993, Appendix, p. A-10, infra.)

Subsequently, the petitioners petitioned the United States Court of Appeals for the Eleventh Circuit for a writ of mandamus[2] directing Judge Pointer to vacate his order denying class certification, hold a hearing on the petitioners' motion for class certification, and enter findings of fact and conclusions of law on the subsequent certification motion. Jurisdiction was invoked under 28 U.S.C. § 1651. The petitioners said: 1) the district court, as part of its responsibility to manage class action, has a duty to hold a hearing on class action certification; 2) Rule 23

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[2] A copy of petition is included in the Appendix, pp. A-12, infra.

requires a hearing when there is any doubt as to the proprietary of certifying the class; 3) a hearing is mandated by due process. (Petition for Writ of Mandamus p. 14, Appendix, p. A-28-49, infra.)

The petitioners also complained that the lower court failed to make any meaningful findings as required by rules 23(c) and 52(a) of the Federal Rules of Civil Procedure. (Appendix, p. A-28-49, infra.) In conclusion, the petitioners urged the Court of Appeals to apply the guidelines promulgated by the United States Court of Appeals in Bauman v. United States District Court, 557 F.2d 650 (9th Cir. 1977) and issue mandamus. On March 11, 1994, the United States Court of Appeals for the Eleventh Circuit denied the petition for mandamus.

ARGUMENT

I. WHETHER THE BASIC ETHICAL STANDARDS FOR HUMAN EXPERIMENTATION DECLARED BY THE NUREMBERG MEDICAL TRIALS IS INCLUDED WITHIN DUE PROCESS CONSTITUTIONAL LAW OR FEDERA COMMON LAW IS AN IMPORTANT QUESTION WHICH SHOULD BE DECIDED BY THIS COURT.

A. Summary of Argument.

The question of whether the Nuremberg Code is encompassed by due process or exists as federal common law is an important issue that should be resolved by this court for three reasons. First, the Nuremberg Code is a natural law document derived from "the principles of the laws of nations as they result from the usages

established among civilized people from the laws of humanity, and from the dictates of public conscience."[3] The Code's ethical standards qualify as common law. Moreover, it qualifies for review to determine whether the principles set forth in the Code are included within the due process guarantee of the fifth amendment of the U.S. Constitution. See United States v. Stanley, 483 U.S. 669, 710 (1987) (J. O'Connor concurring and dissenting). Second, the silicone breast implant litigation is unique in that it is occurring in the form of a nationwide class action. Unless the Code is declared a national ethical standard, thousands of women who have silicone breast implants but who are not yet diseased may not obtain an adequate compensation. Third, this human experimentation is pervasive, something the Nuremberg Code Panel believed must not occur in civilized societies. Thus, there is a compelling need to determine whether the Code is included within federal common law or due process.

B. Lower Court Proceedings.

The Utah class complaint alleged that the Code is the common law ethical standard for human experimentation. The petitioners moved to certify the Utah class, and requested a hearing.

The record shows that the district court's failures to hold a hearing and enter meaningful findings were due to the court's

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U.S. v. Brandt, et al., Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 Vol. II at 183 (1946-49).

inability to appreciate the Nuremberg Code. The district court did not treat the Nuremberg Code as the basic ethical standard for human experimentation. Instead, at a bench conference, the court rejected the claim with alacrity. See the Statement of the Case portion. The Eleventh Circuit Court of Appeals rejected petitioners' request for mandamus. In doing so, it did not rule on the issue of whether the Code is included within due process or common law.

C. Legal Analysis.

1. The Nuremberg Code.

The Nuremberg Code is a statement of ten principles found in the judgment of U.S. v. Brandt, et al.[4] Also called the "Doctor's Trial" or "Medical Case," this trial was conducted at the Palace of Justice in post-war Nuremberg, Germany. The trial covered human experimentation performed by Nazi doctors in both war-related and non-war-related activities. The judgment against the defendants concluded with a ten-point code of ethics on human

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[4] Trials of War Criminals Before the Nuremberg Military Tribunals under Control Council Law No. 10 Vol. II at 181-82 (1946-1949). This case was one of twelve Nuremberg trials prosecuted by the United States on its own, following the War Crimes Trial which was conducted on behalf of the Allied powers. The so-called Nuremberg Principles properly refer to the London Charter, the War Crimes Trial Indictment and the judgment rendered by the Nuremberg Tribunal in the War Crimes Trial. Robert Drinan, "The Nuremberg Principles in International Law," in G. Annas & M. Grodin, eds., The Nazi Doctors and the Nuremberg Code at 174 (1992).

experimentation known as the Nuremberg Code. (Appendix, p. A-7-9, infra.)

The Code is a natural-law document derived from "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience.[5] The Code's principles include: free and informed consent of the subject; adequate prior study and animal experimentation; a purpose for the good of society unobtainable by other methods; and control of the experiment by scientifically qualified persons.[6]

2. Influence of the Nuremberg Code on federal law and regulations.

The Nuremberg Code is the foundation for many U.S. statutes and regulations. In the 1950's, the National Institute of Health (NIH) adopted guidelines applicable to all healthy volunteers. In doing so, the NIH acknowledged that "the rigid safeguards observed at NIH are based on the so-called 'ten commandments'

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U.S. v. Brandt, et al., Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Vol. 11 at 183 (1946-1949).

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Andrew Ivy, "Nazi War Crimes of a Medical Nature," reprinted in W. Curran, Ethics in Medicine: Historical Perspectives and Contemporary Concerns, 270 (1977).

of human medical research which were adopted at the Nuremberg War Crime trials. . . ."[7]

The FDA's entry into regulation of research resulted from the Drug Amendments Act of 1962. In the wake of the thalidomide experience, when no state required physicians to inform patients that they were being given experimental drugs, the 1962 law required experts using such drugs for investigational purposes to inform patients of that fact and generally to obtain their consent.

In 1981, the Food and Drug Administration added new regulations closely modeled on Nuremberg Code principles.[8] They require an investigator who intends to use human research subjects to obtain informed consent.

Federal regulation of human experimentation also took place in other agencies. In 1974, the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with identifying basic ethical principles to govern biomedical and behavioral research involving human subjects. One year later, a comprehensive set of regulations was in place for government sponsored research with fetuses, pregnant women, and

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[7] 49 U.S. Dept. of Health, Education and Welfare, Health Volunteers Help Scientists Conquer Disease, PHS Pub. No. 714 at 14 (1959) (NIH).

[8] 46 Fed. Reg. 8,942 (1981).

in vitro fertilization. The regulations adopted in 1975 included several of the Nuremberg Code's principles.[9]

The Code has also been considered by this Court. Four Justices discussed the Nuremberg Code in United States v. Stanley, 483 U.S. 669 (1987). The case involved LSD experiments conducted by the U.S. military on an unsuspecting army serviceman. The Court, in a split 5-4 decision, ruled that allowing Stanley to recover against the army would constitute judicial disruption of military discipline and autonomy.

The dissenting Justices said that the army's experiment violated not only Stanley's Constitutional rights, but also basic standards of human decency and civilized conduct. The dissenting opinion of Justice Brennan, in which Justices Marshall and Stevens joined, cited the importance of the Nuremberg Code.

> The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects. Its first principle was: "1. The voluntary consent of the human subject is absolutely essential."[10]

Justice Brennan further emphasized that while the military developed the Code, it also applies to civilians.

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[9] 45 C.F.R. 46.206 (1993).

[10] 483 U.S. at 687.

Justice O'Connor, in a separate dissenting and concurring opinion stated that if the Nuremberg Code's principle requiring the subject's voluntary consent is violated, "the very least society can do is to see that the victims are compensated, as best they can be, by the perpetrators." Id. O'Connor concluded that the right to informed consent should be supported by the due process guarantee of the Constitution. Id.

3. Why the Nuremberg Code issues justify judicial review.

a. Introduction.

The Nuremberg Code purports to be a universal common law document.[11] However, in this case the district court ignored the Code. The last time this Court considered the question of whether a federal court was free to disregard common law was in Erie R. R. v. Tompkins, 304 U.S. 64, 71 (1938). The Erie court declared: "There is no federal general common law." Erie at 78. The constitutional thesis of Erie is that the federal judiciary is limited by the constitutional division of governmental power between the federal government and the states. Thus, any assertion by the federal judiciary of a general power to make law encroachs upon the power reserved to the states.

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[11] The Nuremberg Code has been considered to be common law by at least four other courts. See Strunck v. Strunk, 445 S.W.2d 145 (Ky. Ct. App. 1969); Kamowitz v. Michigan Dept. of Mental Health, Civ. No. 73-19434-AW (Mich. Cir. Ct. 1973); Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C. 1986); Pierce v. Ortho Pharmaceutical Corp., 417 A.2d 505 (N.J. 1980).

However, there are at least two reasons why this court may wish to revisit and refine the Erie decision. First, Erie doesn't address what to do when litigation takes the form of a nationwide class action tort claim. In such a form, the litigation requires a nationwide common law standard, something the Nuremberg Code purports to be.

Second, the structure of government proposed by Judge Brandeise's opinion no longer exist in any recognizable form:

> Although the framers may have intended that the federal government would be a government of limited powers, in the years since Erie the Supreme Court has permitted those powers to expand so much that today the federal government has authority to regulate in virtually any area it chooses. In recent years, the only check on this expansion . . . related to state governmental operations and even this check has now been removed.

Merrill, "The Common Law Power of Federal Courts", 52 U. of Chi. L. Rev. 1, 14-15 (Winter 1985).

This petition also provides the Court with an alternative approach. The Court could decline to revisit Erie but declare that the Nuremberg Code is included within and supported by due process, as suggested in Justice O'Connor's concurring and dissenting opinion in United States v. Stanley.

As hereinafter set forth, the silicone breast implant litigation and this country's history of unconscionable human experimentation cry out for review and determination of whether the Nuremberg Code principles are included within our common or constitutional law.

b. The breast implant litigation.

At present, thousands of women have joined as plaintiffs in the multidistrict silicone breast implant litigation. In addition, as set forth in the statement of the case portion of this petition, there is a certified nationwide class action of implant recipients.[12] There is another nationwide class certified for settlement purposes only. Heidi Lindsay et al. v. Dow Corning Corp., et al. Case No. CV-94P-11558-S (U.S.D.C. N.D. of Ala., Honorable Samuel C. Pointer, Jr., presiding). However, only the Utah class action complaint pleads a violation of the Nuremberg Code. The allegations focus on the deficient experimental foundation upon which the implants were mass marketed.

Silicone breast implant recipients should have been protected by the FDA, but they were not. Implants are among the 140 categories of medical devices which manufacturers were supposed to establish as safe under the Medical Device Amendments of 1976.[13] However, in 1978 the FDA chose to rely on the assurances of financially interested plastic surgeons rather than doing its

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[12] Donna Dante, et al. v. Dow Corning, et al., Case No. C-92-057 (U.S.D.C. N.D. of Ala., Honorable Sam C. Pointer, Jr., presiding).

[13] See 21 U.S.C. § 360(c) (1992) (providing that manufacturers of high risk devices introduced before 1976, including breast implants, must prove the safety of the devices prior to continued marketing).

own safety study.[14] The FDA finally requested test data and held public hearings on silicone gel implants in 1991. Serious safety questions were raised decades earlier.[15]

Not only were silicone breast implant recipients not protected by the FDA, they are not all adequately protected in the multi-district implant litigation. Judge Pointer's summary conclusion that the Nuremberg Code claims could be more efficiently handled in existing litigation is incorrect. Because the Nuremberg Code does not require proof of causation or injury, the Code is tailor-made to protect women who are not yet diseased. However, women without disease may not be adequately compensated. A proposed class implant settlement calls for five funds totalling $4.3 billion. (Appendix, p. A-50-64, infra.) However, women who are not diseased and who do not have implant ruptures, are given

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[14]

68 Chi.-Kent. L. Rev. 409, 418. The FDA's complaisance was at least partially the result of insufficient manpower and funding to accomplish the ambitious objectives set out by Congress in the Medical Device Amendments to the Food, Drug and Cosmetic Act.

> . . . in 1976, the FDA's device bureau employed [only] 132 people, including secretaries and file clerks, to review more than 1,700 types of devices. . . . By comparison, 1013 employees were working on ongoing drug review. . . . In 1990, the combined device and radiological center had 860 employees, while the drug center had 1223 employees.

Miolleson, "Consumer Concerns Put Focus on FDA Safety Reviews," Chicago Trib. § 1 at 8 (Jan. 26, 1992).

[15]

See Ingersoll, "Amid Lax Regulation, Medical Devices Flood a Vulnerable Market," Wall Street J. at A6 (March 24, 1992).

access to only two of the compensation funds: the explantation fund and the compensation fund. Each fund will have approximately $722,000,000 ($4.3 billion x. 16.8%). However, since there may be over a million women with implants but no rupture or disease, the compensation contemplated by the agreement could amount to only about $1,444 per person.

If, however, the Nuremberg Code is declared part of the federal common law or due process constitutional law, the women will be armed with a powerful legal theory they can use to secure adequate compensation. They can also obtain an injunction requiring removal to end the experiment.

The Nuremberg Code so provides:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.)

D. Other Human Experimentation.

The Nuremberg Judicial Panel assumed that the Code's principles were basic ethical standards accepted by all civilized societies. However, the recent information and pending release of millions of documents concerning U.S. radiation testing on human subjects

casts doubt on the panel's assumption.[16] The extent of U.S. government involvement in human experiments is considerable:

> In 1977, it was revealed that the CIA, in conjunction with the military, had for 25 years carried out mind control experimentation on unwitting U.S. and Canadian research subjects. . . . Involved were 185 non-government researchers at 80 institutions. . . .
>
> The experimentations ranged from chemical and biological warfare to hypnosis, use of strange pathogens or other toxin agents, and electro-sleep, all designed to elicit secret thoughts. At the hearings conducted by Senators Inouye and Kennedy in 1977, Admiral Stansfield Turner, then CIA director, agreed to set into motion a process which would uncover those unwitting victims and assess damage. This was never done.
>
> From 1980 to 1988, nine Canadians fought a court battle to sue the CIA for funding experiments carried out at McGill University in Montreal in the Allan Memorial Institute, a psychiatric hospital. The experiments, designed to develop brainwashing procedures, had effectively destroyed these victims' lives. . . .
>
> There is more. During the 1950s and '60s, 8000 U.S. servicemen participated in chemical and biological warfare experimentation; 1,000 of these were unwitting recipients of LSD, many others of BZ, a more powerful hallucinogenic drug. The films of men being experi-

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16

On January 25, 1993, the government acknowledged that radiation experiments are still continuing. Secretary O'Leary of the Department of Energy stated before a Senate hearing that she believes all subjects have given informed consent to the procedures, but that victims should be compensated for damages. Some Senate members expressed concern that "rogue researchers" may be conducting experiments without the ethical required consent.

> mented upon are a chilling testament to a callous disregard for human life. . . .
>
> During this century, there have been other examples of the medical profession's collaboration with government agencies in unethical experimentation. Included is the Tuskegee experiment of the Public Health System where 400 poor, black men were denied treatment for syphilis for 40 years so that the natural course of the disease could be followed.[17]

The foregoing examples demonstrate there is a compelling need to determine whether the Nuremberg Code principles are included within the concept of due process or federal common law.

II. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE IMPORTANT ISSUE OF WHEN A UNITED STATES DISTRICT COURT MUST PROVIDE NOTICE AND AN OPPORTUNITY TO BE HEARD PRIOR TO DENYING A MOTION TO CERTIFY THE CLASS.

A. Summary of Argument.

In General Telephone Co. of Southwest v. Falcon, 457 U.S. 147 (1982) the Court criticized the practice of certifying class actions absent a hearing unless it is apparent from the pleadings whether Rule 23 requirements are met. In Eisen v. Carlisle, 417 U.S. 156 (1974), the Court ruled that the district court should not hold a mini-trial on the merits. What remains to be decided is whether due process or F.R.C.P. 23 requires a hearing on the Rule 23 elements in contested class certification proceedings. Since the

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[17] H. Weinstein, "Test Disclosures Show 'Misguided Patriotism,'" San Francisco Chronicle (Jan. 21, 1994) at A23.

issue concerns the construction and application of the Federal Rules of Civil Procedure, which it is the duty of this Court to formulate and put in force, the issue is appropriate for certiorari. See Schlagenhauf v. Holder, 379 U.S. 104, 112 (1964). The importance of the question in the administration of civil justice together with existing uncertainty also warrants certiorari. La Buy v. Howes Leather Co., 352 U.S. 249 (1957).

B. Proceedings in the Lower Court.

As set forth in the statement of the case section, the petitioners twice requested a hearing and twice the district court declined to hold one.

The petitioners filed a petition for mandamus with the United States Court of Appeals for the Eleventh Circuit. (Appendix, p. A-28-49, infra.) In the petition, the Utah plaintiffs said that the district court had a mandamus duty to hold a hearing on the motion to certify the class. They explained that the duty springs from: 1) due process; 2) Rule 23; and 3) the court's duty to conduct, and manage complex class litigation. See Morrison v. Booth, 730 F.2d 642 (11th Cir. 1984).

The Eleventh Circuit Court of Appeals denied mandamus.

C. Legal Analysis.

1. Due process.

At least one Circuit Court of Appeals have ruled that due process requires notice and an opportunity to be heard in contested class certification proceedings. See In re Temple, 851 F.2d 1269, 1272 (11th Cir. 1988).

2. Rule 23.

Rule 23 of the Federal Rules of Civil Procedure requires the petitioners to satisfy the well known touchstones of numerosity, commonality, typicality and adequate representation. In addition, the petitioners must satisfy at least one of the elements of Rule 23(b). These issues, for the most part, are factual issues -- see Sirota v. Solitron Devices, Inc., 673 F.2d 566, 571 (2d Cir. 1982) (numerosity, typicality, commonality) -- or are at least emeshed in factual and legal issues. See e.g., General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 160 (1982).

In those rare cases where it is obvious that Rule 23 requirements exist, the district court may so rule based on the complaint. E.g., General Telephone, supra; Bradford v. Sears, Roebuck and Co., 673 F.2d 792, 795-96 (5th Cir. 1982). However, if there is any doubt as to the propriety of a class action, the district court is required to conduct an evidentiary hearing. E.g., Morrison, supra at 643-44; Bradford, supra at 796.

3. Duty to manage the class action litigation.

The district court has the responsibility, independent of the litigants, to conduct and manage complex class action litigation. Morrison v. Booth, 730 F.2d 642, 644 (11th Cir. 1984); Ezell v. Mobile Housing Board, 709 F.2d 1376, 1380 (11th Cir. 1983). This responsibility includes the duty to hold an evidentiary hearing on the propriety of the litigation proceeding as a class action. Morrison, supra at 643-644; See Ezell, supra at 1380.

III. THE RELATED ISSUES OF WHETHER MANDAMUS MAY BE USED TO REVIEW AND CORRECT CLASS ACTION CERTIFICATION PROCEEDINGS AND, IF SO, UNDER WHAT CIRCUMSTANCES, ARE IMPORTANT QUESTIONS OF FEDERAL LAW WHICH SHOULD BE DECIDED BY THIS COURT.

A. Summary of Argument.

Whether mandamus may be used to review and correct an order denying class action certification is an issue unresolved by this Court. The Sixth, Ninth, Tenth and Eleventh Circuit Court of Appeals have all ruled that mandamus is an appropriate procedural remedy.

This case presents the opportunity to determine whether orders granting or denying class status may be reviewed by mandamus and, along with it, an opportunity to establish uniform criteria for mandamus review.

B. Proceeding Before the Lower Court.

This case has proceeded in a manner comparable to that described in Schlagenhauf v. Holder, 379 U.S. 104, 106-109 (1964). Petitioners moved for class certification and requested a hearing. When a decision was made without a hearing, petitioners sought mandamus to compel a hearing. Since mandamus was denied, petitioners seek certiorari.

C. Legal Analysis.

Orders denying or granting class action certification are not final orders. General Telephone Co., supra. They are not reviewable under 28 U.S.C. § 1291. E.g., Bradford v. Sears,

Roebuck & Co., 673 F.2d 792, 793-94 (5th Cir. 1982). The issue presented in this petition is whether such orders are reviewable via mandamus under the all writs statute (28 U.S.C. § 1651), and if so under what criteria.

Mandamus is traditionally issued by federal courts "to confine an inferior court to a lawful exercise of its prescribed jurisdiction as to compel it to exercise its authority when it is its duty to do so." Roche v. Evaporated Milk Ass'n, 319 U.S. 21, 26 (1943).

The federal courts never confined themselves to a strict definition of jurisdiction, but it is clear that only exceptional circumstances justify mandamus. Will v. United States, 389 U.S. 90, 95 (1967). Schlagenhauf v. Holder, 379 U.S. 109, 110 (1964). Specifically, the writ is invoked when a district court judge displays a persistent disregard of the Rules of Civil Procedure promulgated by this Court. E.g., La Buy v. Howes Leather Co., 352 U.S. 249 (1957).

This Court has not ruled whether mandamus will issue to review and correct defective class certification proceedings, several Circuit Courts of Appeals have declared that mandamus is an appropriate procedural remedy.

In Bauman v. United States Dist. Court, 557 F.2d 650 (9th Cir. 1977), the Court of Appeals for the Ninth Circuit developed five guidelines or factors to determine whether a class action certification proceeding will be corrected by issuing a writ of mandamus. First, the party seeking the writ must lack other adequate means, such as a right of direct appeal, to obtain the

desired relief. The second related factor is whether the petitioners will be damaged or prejudiced in a way not correctable on appeal. The third guideline is whether the district court's order is clearly erroneous. The fourth factor is whether an oft-repeated error occurred or whether the district court manifested a disregard of the federal rules. The fifth factor is whether the certification order raises new and important problems or issues of first impression. Id. at 652-653.[18]

The Ninth Circuit's five guidelines are accepted by the Courts of Appeal for the Sixth and Tenth Circuits. See In re Bendectin Products Liability Litigation, 749 F.2d 300 (6th Cir. 1984); In re Dalton, 733 F.2d 710, 716-717 (10th Cir. 1984). The Eleventh Circuit Court of Appeals adopted a similar analytical framework in In re Temple, 851 F.2d 1269, 1270-71 (11th Cir. 1988), and ordered a hearing on a motion to certify the class.

Since all of the five factors enunciated in Bauman are present in this case, this petition presents an excellent opportunity to define the law of mandamus as it applies to class certification proceedings. Because of the wide implication for the administration of civil justice this issue qualifies for certiorari. See Will v. United States, 359 U.S. 90 (1967).

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[18] Three of the five factors are based on Supreme Court precedent. The first factor is derived from Kerr v. United States District Court, 426 U.S. 394, 403 (1976). The fourth factor comes from La Buy v. Howes Leather Co., 352 U.S. 249, 255-60 (1957). The fifth factor is based on Schlagenhauf v. Holder, 379 U.S. 104, 111 (1964).

IV. WHETHER A DISTRICT COURT HAS A DUTY TO MAKE MEANINGFUL FINDINGS IN SUPPORT OF AN ORDER DENYING CLASS CERTIFICATION IS AN IMPORTANT ISSUE WARRANTING CERTIORARI.

A. Summary of Argument.

F.R.C.P. 52(a) requires a trial judge to make findings of fact and conclusions of law in all civil actions tried upon the facts without a jury. The rule is mandatory and must be reasonably complied with. E.g., Commissioner v. Duberstein, 363 U.S. 278, 292 (1959). This case presents the issue of whether F.R.C.P. 52 (a) applies to orders granting or denying class certification.

B. Lower Court Proceedings.

In response to the petitioners' motion to enter findings of fact and conclusions of law, the district court made a one-paragraph order set forth in the Statement of the Case portion.

However, the Court's sole conclusion is of no consequence. Apparently that lone finding relates to Rule 23(b)(3). It doesn't matter whether the petitioners made the showing required by Rule 23(b)(3) because they clearly met the requirements of Rule 23(b)(2). Hence, the district court made no meaningful findings.

C. Legal Analysis.

When a district court judge rules upon such factual issues, F.R.C.P. 52(a) requires the district court to "find the facts specially and state separately its conclusions of law thereon." The Rule 52 duty to make findings applies to certification proceedings. The district court must make findings on each essential element

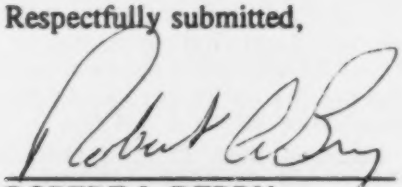
specified in Rule 23. E.g., Bradford v. Sears, Roebuck and Co., 673 F.2d 792 (5th Cir. 1982); Price v. Lucky Stores, Inc., 501 F.2d 1177, 1179 (9th Cir. 1974).

CONCLUSION

The issues raised in this petition desmonstrate special and important reasons for granting certiorari. The issue of whether the Nuremberg Code is included within due process constitutional law or federal common law is an important and basic question of federal law which has not been, but should be, settled by this Court. The other three unresolved issues warrant certiorari because they concern the Federal Rules of Civil Procedure, which it is the duty of this Court to enforce and define.

For these reasons, certiorari to the United States Court of Appeals for the Eleventh Circuit should be granted.

Respectfully submitted,



ROBERT J. DEBRY
Robert J. DeBry & Associates
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

Dated this 9th day of June, 1994.

No.

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

ROBERT J. DEBRY
Counsel of Record
ROBERT J. DEBRY & ASSOCIATES
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

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IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-6130

IN RE:

CONNIE ALBRECHT,
CLAUDIA ARCHULETA,
LYNN ATHERLEY,
MARY JANE BALOK,
SAYY BARELA, et al.,

Petitioners,

- - - - - - - - - -

On Appeal from the United States District Court for the Northern District of Alabama

- - - - - - - - - -

BEFORE: HATCHETT, DUBINA and CARNES, Circuit Judges.

BY THE COURT:

Petitioners' petition for writ of mandamus is denied.

AMENDMENTS TO THE CONSTITUTION

AMENDMENT 5

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

FEDERAL RULES OF CIVIL PROCEDURE

Rule 52. **Findings by the Court; Judgment on Partial Findings**

(a) **Effect.** In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. It will be sufficient if the findings of fact and conclusions of law are stated orally and recorded in open court following the close of the evidence or appear in an opinion or memorandum of decision filed by the court. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rule 12 or 56 or any other motion except as provided in subdivision (c) of this rule.

(b) **Amendment.** Upon motion of a party made not later than 10 days after entry of judgment the court may amend its findings or make additional findings and may amend the judgment accordingly. The motion may be made with a motion for a new trial pursuant to Rule 59. When findings of fact are made in actions tried by the

court without a jury, the question of the sufficiency of the evidence to support the findings may thereafter be raised whether or not the party raising the question has made in the district court an objection to such findings or has made a motion to amend them or a motion for judgment.

(c) **Judgment on Partial Findings**. If during a trial without a jury a party has been fully heard with respect to an issue and the court finds against the party on that issue, the court may enter judgment as a matter of law against that party on any claim, counterclaim, cross-claim or third-party claim that cannot under the controlling law be maintained or defeated without a favorable finding on that issue, or the court may decline to render any judgment until the close of all the evidence. Such a judgment shall be supported by findings of fact and conclusions of law as required by subdivision (a) of this rule.

Proposed Amendment: Subject to Congressional disapproval, the proposed amendment to Rule 52 becomes effective December 1, 1993. The proposed amended Rule 52 provides:

"Rule 52. Findings by the Court; Judgment on Partial Findings

"(a), (b) [Unchanged]

"(c) **Judgment on Partial Findings**. If during a trial without a jury a party has been fully heard on an issue and the court finds against the party on that issue, the court may enter judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated to

render any judgment until the close of all the evidence. such a judgment shall be supported by findings of fact and conclusions of law as required by subdivision (a) of this rule."

Notes of Advisory Committee on September 22, 1992 proposed amendment to Rule. This technical amendment corrects an ambiguity in the text of the 1991 revision of the rule, similar to the revision being made to Rule 50. This amendment makes clear that judgments as a matter of law in nonjury trials may be entered against both plaintiffs and defendants and with respect to issues or defenses that may not be wholly dispositive of a claim or defense.

FEDERAL RULES OF CIVIL PROCEDURE

Rule 23. **Trial by Jury or by the Court**

(a) **Trial by Jury**. Cases required to be tried by jury shall be so tried unless the defendant waives a jury trial in writing with the approval of the court and the consent of the government.

(b) **Jury of less than twelve**. Juries shall be of 12 but at any time before verdict the parties may stipulate in writing with the approval of the court that the jury shall consist of any number less than 12 or that a valid verdict may be returned by a jury of less than 12 should the court find it necessary to excuse one or more jurors for any just cause after trial commences. Even absent such stipulation, if the court finds it necessary to excuse a juror for just cause after the jury has retired to consider its verdict, in the discretion of the court a valid verdict may be returned by the remaining 11 jurors.

(c) **Trial without a jury**. In a case tired without a jury the court shall make a general finding and shall in addition, on request made before the general finding, find the facts specially. Such findings may be oral. If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact appear therein.

THE NUREMBERG CODE OF ETHICS IN MEDICAL RESEARCH

(1) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent: should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural

history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be so conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps in those experiments where the experimental physicians also serve as subject.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facility provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a

continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ALABAMA

ALBRECHT, Plaintiff(s);	)	
vs.	)	No. CV92-P-11104-S
MCGHAN MEDICAL, Defendant(s).	)	

ORDER

Plaintiff's motion that findings of fact and conclusions of law be entered is hereby GRANTED. The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED.

Dated: July 12, 1993.

CHIEF JUDGE SAM C. POINTER, JR.

Service List:
Robert J. DeBry

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

ALBRECHT, Plaintiff(s);	)	
vs.	)	No. CV92-P-11104-S
MCGHAN MEDICAL, Defendant(s).	)	

ORDER

Plaintiff's motion for class certification is hereby DENIED.

Dated: May 25, 1993

CHIEF JUDGE SAM C. POINTER, JR.

Service List:
Robert J. Debry

OFFICIAL TRANSCRIPT
BEFORE THE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In Re:

SILICONE GEL BREAST

IMPLANT PRODUCTS LIABILITY Master File No.

LITIGATION (MDL 926) CV-92-P-10,000-S

Washington, D.C.
Friday, January 22, 1993

HEARING

ALDERSON REPORTING COMPANY, INC.
1111 FOURTEENTH STREET N.W.
SUITE 400
WASHINGTON, D.C. 20005
(202) 289-2260

liability issue. And I death with two cases from South Carolina.

MS. TROUTWINE: Shearman.

THE COURT: Shearman.

MS. TROUTWINE: You told us you were going to do Shearman but you haven't.

THE COURT: No, I have done Shearman.

VOICE: You continued it.

THE COURT: What I did with Shearman was to say that I needed more information and further discovery about whether Recticell does any -- has any principal place of business or note. That was that particular issue.

Those are the only ones that I came prepared to deal with. It is very difficult, as you can imagine, to keep up with the cases in which there is some -- no, I'm sorry, there's one additional one.

The very first one, Albrecht v. McGahn, motion for class certification in 92-11104. There's no effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor --

THE COURT: Before you say anything, I'm going to deny the motion for class certification.

(Laughter)

THE COURT: To the extent that these are

appropriate claims and to the extent we're going to have a class; I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action. that is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory.

MR. WOODSIDE: I would like to report to the Court, now that you have ruled that way, you are consistent with several State courts in Utah which have ruled similarly in similar actions by Mr. DuVries.

THE COURT: I wonder if there's been any inadequate opportunity for plaintiffs' counsel and Baxter to discuss matters about the attorneys fee, the quantum of attorneys fees and expenses? Can we deal with it separately? Or whichever way you want to do it.

MR. KNOWLES: Judge, let me report, we did talk by the problem is, as you recognized even not knowing it, we spent almost no time worrying about the -- this is not to say we want to waive it, but worrying about the issue of calculating our fees and expenses.

I have some rough numbers on that, but I think that probably the more appropriate way to do it would be within the next few days, to send to Debra, and then if she can have a few days to object if she wants. Although Debra said she wanted us to provide affidavits and

October 30, 1992

Honorable Sam C. Pointer, Jr.
United States District Judge
U.S. District Court
Federal Courthouse
Birmingham, AL 35203

In Re: Silicone Gel Breast Implants Products Litigation (MDL-926)

Listing of Motions Which Merit Early Attention

Master File No. CV92-P-10000-S

Honorable Sir:

On October 6, 1992, your clerk, Jonathan Banks, wrote to all parties in MDL 926 requesting a list of motions which merit early attention. Pursuant to that request, we suggest that the following motion merits early attention.

Case Name:	Albrecht et al. v. McGhan Medical Corp. et al.
Case Number: (originating unit)	92-C-0089J
Name of Motion:	Motion for Class Certification Respecting Counts XII, XIII, AND XIV. (Defendant Dow Corning only.)
Suggested Briefing Schedule:	Plaintiffs' motion and supporting memorandum has been filed. Plaintiffs suggest that defendant Dow Corning have 30 days to file an opposing memorandum, and that plaintiffs have 15 days to file a reply memorandum. A hearing could be scheduled for December or early January.
Reasons That This Motion Merit Early Attention:	A class action has already been certified in the case of Dante v. Dow Corning by Judge Rubin. That existing class action has

been transferred to the Northern District of Alabama pursuant to MDL Order 926. This case (Albrecht) seeks certification for claims and theories not presently included in the Dante case. (viz. battery and violations of the Nuremberg Code.) If granted, this pending motion would have enormous impact on every aspect of the consolidated cases. All pending issues of discovery, trial preparation, notice, etc., would be affected by the Albrecht case

We attach for the Court's consideration a copy of the Complaint, the Motion For Class Certification Respecting Counts XII, XIII, and XIV, plus the supporting memorandum.

Finally, in Order No. 1, this Court requested counsel to submit "preliminary reports" to familiarize the Court with each case (or group of cases). Of course, this case had not yet been filed when Order No. 1 was signed (June 26); Therefore, there was no "preliminary report" to acquaint the Court with this case. Therefore, this letter, with attachments, would serve the dual role of identifying motions for early consideration, plus a "preliminary report" to acquaint the Court with this case. Thank you for your consideration in this matter.

Sincerely,

ROBERT J. DEBRY & ASSOCIATES

Robert J. DeBry

RJD/sc
Attachments

cc: Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

June 7, 1994

Honorable Sam C. Pointer, Jr.
U.S. District Court
Northern District of Alabama
U.S. Courthouse
Birmingham, AL 35203

RE: Urgent Request to Set Hearing Date in the Case of Albrecht v. McGhan Medical, et al. (92-P-11104-S)

Dear Judge Pointer:

On October 29, 1992, plaintiffs filed a Motion for Class Certification in this case. (See Exhibit A.) No hearing date has been set. Recent events suggest an urgent need to set a hearing date on this pending motion.

OVERVIEW OF PENDING MOTION

As the Court is aware, a class has already been certified in the case of Donna Dante v. Dow Corning, et al.,. (hereafter the "Dante class").

The pending motion in this case (Albrecht) (hereafter the "Albrecht class") seeks to certify a class with respect to three special issues which do not fall under the existing Dante class. Specifically, Albrecht sets up claims for continuing common law battery, for unlawful human experimentation in violation of principles of the Nuremberg Code[1]; and for violations of the Magnusson-Moss Warranty Act.

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1 United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal, Vol. I and II. The Medical Case. Washington, D.C., U.S. Government Printing Office. (1948).

Rule 23(c)(4)(A) specifically authorizes the creation of such classes for special issues:

> An action may be brought or maintained as a class action with respect to particular issues.

See Also Manual on Complex Litigation, Second § 30.17.

DISTINCTIVE ASPECTS OF THE PROPOSED ALBRECHT CASE

The proposed Albrecht class adds three important concepts to this consolidated litigation.

First, in order to win a case for violations of the Nuremberg Code, it is not necessary to show causation. That is, it is not necessary to show that the breast implant caused some physical injury. Rather it is only necessary to show that informed consent was lacking or defective. The remedy for violations of the Nuremberg Code is to give women the option to "bring the experiment to an end." (See Nuremberg Code at para. 9.) Or, stated in other words, to give women an option to have the breast implants removed.

Second, the theory of battery is in reality a claim for "continuing battery." That is, the unconsented touching continues so long as the breast implant remains in the woman's body. Note that (as in the case of Nuremberg Code violations) it is not necessary to prove causation to win a claim for common law battery. Rather it is only necessary to prove an unconsented touching.[2] The remedy for such an unconsented touching is simply to end the continuing battery. Or stated in other words, to give women the option to have the breast implants removed.

Third, because the unconsented touching continues, statutes of limitations have not yet begun to run.

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2 Of course if the unconsented touching causes physical injury, an additional element of damages is present.

RELATIONSHIP OF LEGAL THEORIES IN ALBRECHT CLASS AND THE DANTE CLASS

The Dante class pleads claims for bodily injury caused by the breast implants. The complaint also pleads a "medical monitoring fund." However that fund is to compensate women who "are likely to suffer" some future bodily injury.[3]

In contrast, the Albrecht class includes claims for women who simply want to have the breast implants removed (or the financial equivalent of removal).[4] In effect, the Albrecht class would operate as a sort of nationwide recall of the defective breast implants for women who can and do allege injuries in excess of $50,000.

A simple analogy might be an automobile with a defective part. Traditional tort theories would recover for personal injuries caused after the defective part causes a crash. However, society

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[3] The order certifying Dante describes the class as: "a) Such persons who as a result of the silicone gel breast implant have sustained any adverse medical condition thereby; and b) those persons who are likely to suffer or are at an increased risk of suffering any adverse medical condition as a result of having received a silicone gel breast implant, and who may be in need of medical monitoring to facilitate early detection of any such future condition." (See Exhibit B and C.)

[4] point of fact, the Albrecht complaint covers claims for women who can in good faith allege injuries in excess of $50,000. There is pending in Utah state court a Jane Doe nationwide class action, not yet certified, which pleads for rescissory damages for less than $50,000 for women who have not previously made a claim in a legal action against Dow Corning for tortious bodily injuries and who simply seek compensation sufficient to cover the costs of their original implants and expenses in again consulting a physician or surgeon, hospital costs, and other actual medical expenses involved.

is ill served if people must continue to drive the defective cars (or to bear the defective breast implant) until an injury occurs. Society is better served by a nationwide recall to replace or repair the faulty part (or breast implant) before injury occurs.

Although admittedly an oversimplification, the Dante class might be seen to encompass 1% of all women who have ever had breast implants. (viz. those women who can prove a bodily injury or who are "likely" to suffer a future bodily injury.) However, 100% of the women who have ever received breast implants may be entitled to damages under theories of common law battery, violations of the Nuremberg Code, and violations of the Magnusson-Moss Warranty Act. (viz. a nationwide recall of a defective product.)

Finally, it is entirely possible that the Dante class may lose at trial because they cannot meet the burden of causation; while at the same trial, the proposed Albrecht class may win because causation is not an issue for common law battery, or for violations of the Nuremberg Code, or for violations of the Magnusson-Moss Warranty Act.

GENERAL STANDARDS FOR EARLY RULING

Rule 23(c)(1) provides that class certification shall be determined "as soon as practicable." (See also Manual on Complex Litigation, Second, § 30.11.) However, the issue here is more fundamental. The issue is simply getting the matter on the Court's calendar. Rule 78, Federal Rules of Civil Procedure provides:

> Unless local conditions make it impracticable, each district court shall establish regular times and places, at intervals sufficiently frequent for the prompt dispatch of business, at which motions requiring notice and hearing may be heard and disposed of. . . .

This Court certainly has great latitude in administering that rule. However, the spirit of the rule contemplates that matters will not be held in abeyance for any extended time. The Manual on Complex Litigation, Second provides similar guidance at § 21.32:

> . . . potentially meritorious motions -- particularly those which, if granted, would substantially affect further proceedings in the litigation -- should be welcomed by the Court and given prompt attention. (Emphasis added.)

NEED FOR URGENT ACTION

This letter to the Court is triggered by a Breast Implant Bulletin which has recently been circulated. (See Exhibit D.) The Bulletin describes "secret negotiations" which may be underway to settle the pending class action. Presumably those settlement negotiations would settle the Dante claims.

However, the Dante class can only negotiate to settle claims distinctive to that action. That is to say, the Dante class cannot, somehow, negotiate for a global settlement to include claims (such as continuing battery or violations of the Nuremberg Code) not included in the Dante complaint and other unique classes of claimants.

> Occasionally the parties propose a settlement covering a class different from that certified. Typically, the parties propose to enlarge the class--or the claims of the class --to give the settling defendants greater protection against further litigation. . . . The problem presented by these requests is not the lack of sufficient information and scrutiny, but rather the possibility that fiduciary responsibilities of class counsel or class representatives may have been compromised.

Manual on Complex Litigation, Second, § 30.45.

Therefore, any settlement of the Dante claims would, of necessity, be a partial settlement. Claims in the Albrecht class and in the Jane Doe nationwide Utah state class would remain to be litigated another day. However, the Manual gives special warning about the problems of a partial settlement (See Manual on Complex Litigation, Second at § 30.46). Steps should be taken that this in reality will not be just a partial settlement depleting available funds. (See Manual on Complex Litigation, Second, at §§ 30.212 and 30.44.) Moreover, substantial confusion would certainly arise if women were to receive notice of a settlement in Dante (for

injuries) before they are ever aware that they may have rights even though they may not have suffered any bodily injury (viz. the Albrecht class).

In summary, this Court should urgently hold hearings regarding any sub-classes or special classes. Only after the metes and bounds of the class are known, can settlement discussions be fairly conducted for the benefit of all women who have received the defective breast implants.

Sincerely,

ROBERT J. DEBRY

RJD/vah
Attachments

cc: Plaintiff's Liason Counsel
Defendant's Liason Counsel

IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, individually, Plaintiff, vs. McGHAN MEDICAL CORP. INAMED CORP., HEYER-SCHULTE CORP., AM HOSPITAL SUPPLY CORP., BAXTER HEALTH-CARE CORP., BAXTER INC., MENTOR CORP., and DOW CORNING CORP. CORPORATION, Defendants.	**SECOND AMENDED COMPLAINT (CLASS ACTION[1]) (JURY TRIAL DEMANDED)** Case No. 92-C-0889J Alabama Case No. 92-P-11107-S Judge Bruce S. Jenkins MDL Judge Sam C. Pointer

1

Counts I-XI are pleaded as individual claims. Counts XII, XIII and XIV are pleaded as a class action. See, Rule 23(c)(4)(A) F.R.C.P.

COUNT XIII

UNLAWFUL HUMAN EXPERIMENTATION

82. Plaintiffs reallege each and every paragraph and allegation above as if fully set forth herein.

83. The Nuremberg Code[2] is a part of international law ratified by the United Nations General Assembly and to which the United States is a consenting party; it effectively sets a minimum standard of care by governments and institutions and individuals therein with regard to experimentation on human beings.

84. The Nuremberg Code inter alia provides that:

> The voluntary consent of the human subject is essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> The experiment should be so designed and based upon the results of animal experimentation... that the anticipated results will justify the performance of the experiment.

[2] United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal, Vol. I & II, The Medical Case.

* * *

> The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

* * *

> Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

Nuremberg Code at paragraphs 1, 3, 4 and 6.

85. Defendant Dow Corning Corporation violated each of the aforesaid provisions of the Nuremberg Code in that:

a. Dow Corning Corporation failed to make known to plaintiffs and the putative class members that no adequate human testing had ever been conducted; and that by marketing the silicone gel breast implants without adequate human testing, Dow Corning Corporation and Dow Corning Wright were, in effect, conducting a gigantic human experiment on plaintiffs and the putative class without their knowledge or consent.

b. Defendant Dow Corning Corporation conducted some animal tests on silicone gel and silicone gel breast implants; however, the results of those animal studies did not justify experiments on human beings. Furthermore, many of the animal experiments yielded negative or adverse results; which Dow Corning Corporation did not reveal to plaintiffs or the putative class members.

c. Dow Corning Corporation had absolute knowledge that the use of silicone gel breast implants would cause unnecessary physical and mental suffering and injury in some persons;

however, Dow Corning Corporation nonetheless, continued the experiment on plaintiffs and the putative class. Furthermore, Dow Corning Corporation did not disclose the risks of unnecessary physical and mental suffering and injury as required by the Nuremberg Code.

d. Dow Corning Corporation did not make adequate preparation to protect plaintiffs and the putative class from the possibility of injury, disability and death as required by the Nuremberg Code.

86. By reason of Dow Corning Corporation's violations of the Nuremberg Code, plaintiffs and the putative class have been surgically implanted with silicone gel breast implants that have never been fully tested on animals or human beings. Therefore, plaintiffs and the putative class members have been injured in that they have, without their consent, suffered physical pain, emotional distress and expenses of surgery and hospitalization. Moreover, plaintiffs and the putative class members have become unwitting subjects of a gigantic and dangerous experiment on human beings. By reason of such injuries plaintiffs and the class members they represent should be entitled to money damages; and in addition, they should be entitled to invoke the provisions of paragraph 9 of the Nuremberg Code which states:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

87. The defendant's violations of the Nuremberg Code were done with reckless disregard for the rights and safety of the representative plaintiffs and putative class members. Furthermore, the defendant's failure to fully disclose the information, risks and lack of safety studies on their implants prevented the representative plaintiffs and putative class members from discovering the unlawful human experimentation until within the past year, nor could they have discovered or been obliged to try to discover such through their own diligence at any time sooner.

COUNT XIV

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT

88. Plaintiffs reallege each and every paragraph and allegation above as if fully set forth herein.

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

IN RE CONNIE ALBRECHT, et al.,	)	
Petitioners,	)	No. _____

PETITION FOR WRIT OF MANDAMUS

ROBERT J. DEBRY & ASSOCIATES
ROBERT J. DEBRY, Esq. (A0849)
DEBRA A. ROBB (A5629)
4252 South 700 East
Salt Lake City, UT 84107
Telephone: (801) 262-8915

WALLACE R. BENNETT, Esq. (A0286)
1723 South 2100 East
Salt Lake City, UT 84108
Telephone: (801) 581-1516

D. FRANK WILKINS, Esq. (A3468)
BERMAN, GAUFIN & TOMSIC
50 South Main, #1250
Salt Lake City, UT 84144
Telephone: (801) 328-2200

DAVID D. BENNETT, Esq. (A5917)
SCIENCE & LAW RESEARCH INST.
633 South 800 East
Salt Lake City, UT 84102
Telephone: (801) 521-4065

The petitioners, pursuant to 28 U.S.C. § 1651 and Rule 21(a) of the Federal Rules of Appellate Procedure, apply for a writ of mandamus directing the Honorable Samuel C. Pointer, Judge of the United States District Court for the Northern District of Alabama, Southern Division: (1) to vacate his order (copy attached as Exhibit 1) denying class action status to the petitioners; (2) to hold an evidentiary hearing on the petitioners' motion for class certification; and (3) to enter findings in support of any subsequent decision of the petitioners' Motion for Class Certification. In support of this application, the petitioners state:

III.

ORDER ENTERED BELOW

On July 12, 1993, the respondent, without the benefit of notice or hearing, entered an order denying class action certification to the petitioners. A copy of the order is attached as Exhibit 1.

IV.

STATEMENT OF THE FACTS NECESSARY TO AN UNDERSTANDING OF THE ISSUES PRESENTED IN THIS APPLICATION

The facts necessary to an understanding of the issues presented in this application follow:

A. The Utah Action.

The petitioners are 123 women who each received silicone breast implants supplied by Dow Corning Corp. The petitioners filed their lawsuit, as a class action, in the United States District Court for the District of Utah in October of 1992. The Utah action is titled Albrecht, et al. v. McGhan Medical Corp., et al.

(hereafter Albrecht). The petitioners seek to represent a nationwide class of approximately one million similarly situated women. A copy of the petitioners' Motion for Class Certification with Supporting Memorandum is attached as Exhibit 2.

Before a hearing could be held on the petitioners' motion to certify the class, the case was transferred to the United States District Court for the Northern District of Alabama, Southern Division, pursuant to 28 U.S.C. § 1407.

B. The Ohio Action.

A parallel suit was filed in the United States District Court for the Southern District of Ohio, Western Division under the name of Donna Dante, et al. v. Dow Corning Corp., et al (hereafter, Dante). The Ohio case was also filed as a class action. However, unlike the Utah action, the Ohio court had time to hold hearings on class certification before the case was transferred. A nationwide class was certified by the Ohio court. (See Exhibit 3.) Thereafter the case was transferred to the Northern District of Alabama pursuant to 28 U.S.C. § 1407.

C. The Multi-District Action.

As noted, above, the Utah action (Albrecht) and the Ohio action (Dante) as well as hundreds of other cases throughout the country were transferred to the Northern District of Alabama pursuant to 28 U.S.C. § 1407. Thus, Judge Samuel C. Pointer inherited an amalgamation of breast implant cases from all over the United States, including:

1. A nationwide class action (Dante) which was certified in Ohio before transfer to Judge Pointer;
2. A class action complaint (Albrecht) in which no hearing was held on class certification before transfer to Judge Pointer; and
3. Thousands of individual lawsuits.

D. Distinctive Features of the Utah Action.

In many respects, the Utah complaint (Albrecht) and the Ohio complaint (Dante) are identical. However, the Utah complaint (Albrecht) pleads three distinct causes of action not found in the Ohio (Dante) action. The petitioners seek to have these three unique claims certified pursuant to Rule 23(c)(4)(A).[1]

The first unique aspect of Albrecht is a claim for continuing battery. (Amended Complaint paras. 77-81.) To establish their battery claims, the petitioners need only show an offensive contact. See generally, Restatement (Second) of Torts, §§ 13-20. Moreover, since the breast implants remain in the petitioners' bodies, the battery continues. Finally, the basic measure of damages the petitioners seek is the cost of ending the battery, that is, the cost of removing the implants. (Amended Complaint p. 115 para. 6.)

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[1] "When appropriate . . . an action may be brought or maintained as a class action with respect to particular issues." Manual for Complex Litigation § 30.17 at 207 (2d Ed. 1986).

The second unique aspect of Albrecht is a claim for unlawful human experimentation. (Amended Complaint paras. 82-87.) The legal foundation for the petitioners' claims is the Nuremberg Code. Basic ethical standards for all human experimentation were declared in the Nuremberg War trials. "[T]he [Nuremberg] code is part of the international law . . . and international law is part of our law. . . ." G.J. Annas, The Law of Informed Consent to Human Experimentation: Preliminary Report Prepared for the National Committee for the Protection of Human Subjects of Biomedical Research, 11 (1976). The Nuremberg Code is also accepted as a basic ethical standard by federal courts. See, United States v. Stanley, 483 U.S. 669, 687 (1987) (J. Brennan, concurring and dissenting); Whitlock v. Duke University, 637 F. Supp. 1463, 1470 (M.D.N.C. 1986); Kaimowitz v. Dept. of Mental Health, 1 Mental Disability L. Rep. 147 (Mich. Cir. Ct. 1973); W.J. Curran, *Legal Codes in Scientific Research Involving Human Subjects*, 34 Lex. Et. Sciemtia, 65 (1966).

The Nuremberg Code explicitly provides:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon

> his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> The experiment should be so designed and based upon the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

(Nuremberg Code at paragraphs 1 and 3.)

The petitioners' complaint alleges that adequate animal tests were not conducted; and that Dow Corning did not reveal all of the known risks and side effects to women who received the breast implants. (Amended Complaint para. 85.) In effect, the petitioners allege that they are subjects of mass human experimentation.

The Nuremberg Code also provides the appropriate remedy:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.)

Under the Nuremberg Code theory, the petitioners seek a mandatory affirmative injunction requiring Dow Corning to inform all recipients of Dow Corning breast implants of the known risks and side effects. After being fully informed, each woman will have an opportunity, at her election, to "bring the experiment to an end" by having the implants removed at Dow Corning's expense.

The third unique aspect of Albrecht is a claim under the Magnusson-Moss[2] Warranty Act. (Amended Complaint paras. 88-103.) The petitioners claim that Dow Corning breached the implied warranty as defined in 15 U.S.C. § 2301(7) and express warranties as defined in 15 U.S.C. § 2301(6). Unlike the class claims in Dante, the petitioners also claim attorneys' fees under 15 U.S.C. § 2310(d)(2).

The differences between the Dante complaint and the Albrecht complaint are more than theoretical. There are monumental practical differences! To begin with, the Dante complaint covers women who have received some bodily injury from the implant. However, many women have not yet suffered a bodily injury. Rather, they want to get the breast implant out before the injury occurs. The Albrecht class action would cover the latter group.[3] Moreover, in order to win their claims, each plaintiff in the Dante class action must prove that the breast implant caused their bodily injury. This causation issue is very difficult indeed. However, causation is not a necessary element to make out a cause of action

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Frank E. Moss, co-author of the Magnusson-Moss Warranty Act is a member of the attorney team in Albrecht.

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The Albrecht complaint also includes some women who claim actual bodily injury. The petitioners do not seek to certify those injury claims as a class action. Rather, the injury claims would be subsumed under the Dante class. See generally p. 2 and 3, above.

for battery or violation of the Nuremberg Code. In short, the Albrecht claims are simply easier to prove at trial.

E. Proceedings in the Northern District of Alabama.

Upon receiving the breast implant litigation, Judge Pointer requested the litigants to identify motions that should be ruled upon early in the litigation. In response to Judge Pointer's order, the petitioners notified the Court that there was a pending motion to certify the Albrecht (Utah) lawsuit as a class action. The petitioners requested a hearing on their motion. (Exhibit 4.)

However, Judge Pointer did not hold a hearing on the petitioners' motion to certify the class action. Instead, without any notice, without any arguments, and in a bench conference with other counsel, the Court made the following ruling from the bench:

THE COURT: The very first one is Albrecht v. McGhan motion for class certification is 92-11104. There's an effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor.

THE COURT: Before you say anything, I am going to deny the motion for class certification.

(Laughter)

THE COURT: To the extent that these are appropriate claims and to the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain of these limited theories of action.

Transcript of Proceedings of January 2, 1993, p. 161, lns. 17-25; p. 162, lns. 1-4.[4]

Being unaware that the Court had even made such a bench ruling, the petitioners' counsel again requested a hearing (Exhibit 6). However, the Court did not hold the requested hearing, and in a one sentence order ruled:

> "Plaintiffs' Motion for Class Certification is hereby denied."

Order No. 11, entered May 25, 1993. (See Exhibit 7.)

Because of the perfunctory nature of the May 25 order (Exhibit 7), the petitioners filed a "Motion that Findings of Fact and Conclusions of Law be Entered." (Exhibit 8.) Again, no hearing was held, but the Court entered a new order stating:

> Plaintiff's motion that findings of fact and conclusions of law be entered is hereby GRANTED. The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED. (Exhibit 1.)

The petitioners file this application to compel the lower court to hold a hearing and to enter meaningful findings on the petitioners' motion to certify the class.

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[4] A copy of the transcript is attached as Exhibit 5.

V.

ISSUES PRESENTED

The issues presented by this application are:

1. Whether the district court has a mandatory duty to conduct an evidentiary hearing on class certification when, as in this case: (a) all Rule 23 requirements are apparently met; (b) the court denies certification on a ground which is not specified in F.R.C.P. 23; (c) the moving parties have not had an opportunity to address the ground identified by the district court for its decision denying class certification; and (d) as a practical matter the parties are denied the opportunity to litigate the ground used by the district court to deny certification?

2. Whether the district court has a mandatory duty to enter meaningful findings on its class certification ruling?

3. If the duties exist, will mandamus issue to compel the required hearings and findings?

VI.

RELIEF SOUGHT

The petitioners seek a writ of mandamus directing the lower court to: (1) vacate the order denying class action certification; (2) hold an evidentiary hearing on the petitioners' motion for class certification; and (3) enter findings of fact and conclusions of law on the subsequent certification ruling.

VII.

REASONS WHY THE WRIT OF MANDAMUS SHOULD ISSUE

A. Under the Circumstances That Exist in This Case the District Court Had a Mandatory Duty to Conduct an Evidentiary Hearing on the Petitioners' Motion to Certify the Class.

1. The district court, as part of its responsibility to manage the class action litigation, has a duty to hold a hearing on class action certification.

The district court has the responsibility, independent of the litigants, to conduct and manage complex class action litigation. Morrison v. Booth, 730 F.2d 642, 644 (11th Cir. 1984); Ezell v. Mobile Housing Board, 709 F.2d 1376, 1380 (11th Cir. 1983). This responsibility includes the duty to hold an evidentiary hearing on the propriety of the litigation proceeding as a class action. Morrison, supra at 643-644. See Ezell, supra at 1380. The court is required to conduct an evidentiary hearing with or without a motion from counsel. Satterwhite v. City of Greenville, 578 F.2d 987, 993 n. 7 (5th Cir. 1978). The court has an independent duty to hold the certification hearing as early as practicable. Cruz v. Hauck, 627 F.2d 710, 716 (5th Cir. 1980).

2. The Rule 23 criteria for certifying the class requires an evidentiary hearing when there is any doubt as to the propriety of certifying the class.

Rule 23 of the Federal Rules of Civil Procedure requires the petitioners to satisfy the well known touchstones of numerosity, commonality, typicality and adequate representation. Federal Rules of Civil Procedure 23(a)(1-4). In addition, the petitioners must satisfy at least one of the elements of Rule 23(b). These issues, for the most part, are factual issues. See Sirota v. Solitron

Devices, Inc., 673 F.2d 566, 571 (2d Cir. 1982) (numerosity, typicality, commonality).

To resolve the Rule 23 issues, the court first examines the complaint. In those rare cases where it is obvious that the Rule 23 requirements exist or do not exist, the district court may so rule based on the complaint.[5] E.g., Lewis For and On Behalf of Lewis v. Heckler, 752 F.2d 555, 557 (11th Cir. 1985); Bradford v. Sears, Roebuck and Co., 673 F.2d 792, 795-96 (5th Cir. 1982). However, if there is any doubt as to the propriety of a class action, the district court is required to conduct an evidentiary hearing. Morrison, supra at 643-44; Bradford, supra at 796; see Madison v. Miss. Medicaid Comm'n, 86 F.R.D. 178, 185 (N.D. Miss. 1980). Simply put, the lower court should not deny class certification without providing the plaintiff an evidentiary hearing if it is requested. Marcera v. Chinlund, 565 F.2d 253, 255 (2d Cir. 1977).

3. A hearing is required when the district court bases its decision on something other than the Rule 23 criteria.

The district court's duty to hold an evidentiary hearing is mandated when, as here, the court does not base its denial on a

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"[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action. (Citations omitted.) Sometimes the issues are plain enough from the pleadings . . . and sometimes it may be necessary to probe behind the pleadings before coming to rest on the certification question." General Telephone Co. of the Southwest v. Falcon, 457 U.S. 147, 160 (1982).

failure to meet Rule 23 requirements. Morrison, supra at 644. In this case, the lower court concluded, without a hearing, that the petitioners' claims can be better managed in existing litigation. However, a well developed factual record is particularly important where class certification is challenged on the asserted ground that, in cases like this one, the proposed class action is unmanageable or can be managed better in some other litigation. Bryant v. Food Lion, Inc., 774 F.Supp. 1484, 1495 (D.S.C. 1991). As explained by the Courts of Appeals for the Third and Fourth Circuits:

> 'Before a ruling is made denying class action certification . . . hard data should be presented to the district court as to the actual difficulty - or ease - involved in determining class membership and managing the class proceeding.' Windham v. American Branch, Inc., 565 F.2d 59, 64 n. 5 (quoting Neeley v. United States, 546 F.2d 1059, 1071 (3d Cir. 1976).

In this litigation there is no hard data supporting or discrediting the lower court's conclusion that the petitioners' claims "can be dealt with more efficiency in other existing litigation." (Exhibit 1.) There is no data because the court failed to perform its mandatory duty of holding a hearing.

For example, the lower court ruled that the class claims in Albrecht (viz. battery and Nuremberg Code violations) " . . . can be dealt with most efficiently in other existing litigation . . ." (See Exhibit 1. Emphasis added.) However, it is not clear what "other existing litigation" the Court is talking about. Nor is it clear why it is more efficient to resolve these claims in the "other existing litigation."

4. A hearing is mandatory if there is a substantive certification issue and without a hearing the moving party, will be denied the opportunity to litigate it.

The fundamental concepts of notice and an opportunity to be heard apply to class action certification proceedings. In re Temple, 851 F.2d 1269, 1272 (11th Cir. 1988). A hearing is mandatory in situations where, as here, there are substantive certification issues and the moving party will be denied an opportunity to litigate it. E.g., Temple, supra; Falcon v. General Telephone Co. of Southwest, 626 F.2d 369, 374 (5th Cir. 1988).

The fundamental certification issue identified by Judge Pointer in this case is manageability. (See Rule 23(b)(3).) As set forth in the Statement of Facts section, the petitioners' claims in the Utah (Albrecht) action are separate and distinct from the claims which have been certified in the parallel Ohio (Dante) class action litigation. "Differences in claims can create conflicts in pre-trial, trial and settlement." J.W. Moore, Manual for Complex Litigation § 30.16 at 205, 206 (2 Ed. 1986). In addition, the relief sought by some claimants often competes with relief sought by others. Id. In this case, the petitioners seek injunctions to end the unlawful batteries and experiments. Injunctive relief is not sought in the parallel Dante litigation. The appropriate remedy for substantial differences is to create the subclass requested by the petitioners. See id. However, by declining to notify the petitioners in advance of its ruling and by declining to hold a hearing, the district court

precluded the petitioners from ever litigating the manageability and conflicts issues.[6]

B. The District Court Has a Mandatory Duty to Make and Enter Findings in Support of Its Certification Decision.

1. The lower court did not make any meaningful findings.

As set forth in page 11 of this petition, the class certification issues raised by Rule 23 are mostly factual issues. The Court, by order, determines whether a case qualifies as a class action. Federal Rules of Civil Procedure 23(c). When the Court rules upon such factual issues, Rule 52(a) of the Federal Rules of Civil Procedure requires the district court to "find the facts specially and state separately its conclusions of law thereon." The duty to make the findings required by Rule 52 is mandatory. E.g., H. Prang Trucking Co., Inc. v. Local Union No. 469, 613 F.2d 1235 (3d Cir. 1980); see United States By Clark v. Gramer, 418 F.2d 692, 693 (5th Cir. 1969) and it applies to certification proceedings.

> The judge should enter findings and conclusions after the hearing, addressing each of the applicable requirements of Rule 23(a) and (b).

Manual for Complex Litigation, supra § 30.13 at 202.

In determining whether a lawsuit should proceed as a class action, the district court must make findings on each essential

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[6] See footnote 1, above.

element specified in Rule 23.[7] E.g., Bradford v. Sears, Roebuck and Co., 673 F.2d 792 (5th Cir. 1982); Price v. Lucky Stores, Inc., 501 F.2d 1177, 1179 (9th Cir. 1974); Beebe v. Pacific Realty Trust, 99 F.R.D. 60, 64 (D. Ore. 1983).

In this case, the district court did not make a finding on each of the Rule 23 elements. It did not make a finding at all. All it did, was make a one sentence conclusion that this litigation could be more efficiently handled with other class action litigation.

Rule 52 is not satisfied by a statement of ultimate fact. E.g., H. Prang Trucking, supra; Smith v. Dental Products Co., 168 F.2d 516, 518 (7th Cir. 1948). Most of the Circuits require that the district court's finding on the ultimate issue of fact be supported by subsidiary fact findings. See e.g., O'Neil v. United States, 411 F.2d 139, 146 (3d Cir. 1969); McIntosh County Branch of NAACP v. City of Darien, 605 F.2d 753, 757 (5th Cir. 1979); Deal v. Cincinnati Board of Education, 369 F.2d 55, 64 (6th Cir. 1966); Kweskin v. Finklestein, 223 F.2d 677 (7th Cir. 1951); Van Borg, Allen, Weinberg and Rogers v. N.L.R.B., 656 F.2d 1356 (9th Cir. 1981); and Wood's Construction Co. v. Pool Construction Co., 314 F.2d 405 (10th Cir. 1963).

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[7] A court's resolution of the class action issue is not entitled to the deference due such a determination when it is supported by findings as to the application of Rule 23 criteria. Gibson v. Local 40 Supercargoes & Checkers, etc., 543 F.2d 1259, 1263 n.2 (9th Cir. 1976).

When the district court fails to comply with the letter and spirit of Rule 52(a), the remedy is to remand for compliance. E.g., Lemelson v. Kellogg Co., 440 F.2d 986 (2d Cir. 1971); Squirt Co. v. Seven Up Co., 628 F.2d 1086 (8th Cir. 1980).

2. The one unsupported finding or conclusion the court did make is of no consequence.

The trial court entered a one sentence conclusion that the class claims in Albrecht can be more efficiently handled in other litigation. Apparently that lone finding relates to Rule 23(b)(3).[8]

However, the Court's sole conclusion is of no consequence. It doesn't matter whether the petitioners make the showing required by Rule 23(b)(3) because they clearly meet the requirements of Rule 23(b)(2). As set forth in page 11 of this application, after the petitioners satisfy the Rule 23(a) requirements, they need only satisfy one of the Rule 23(b) requirements.

In summary, it simply makes no difference whether or not the class claims (viz. battery and Nuremberg Code) in Albrecht can be

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[8] "[T]he court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action."

more efficiently handled in other existing litigation because that is a Rule 23(b)(3) consideration. Since the class can and should be certified under Rule 23(b)(2), the Court has no reason to make Rule 23(b)(3) findings.

C. Mandamus Should Issue to Order the Required Hearing and Findings.

Mandamus has traditionally been used to compel inferior courts to exercise their authority when it is their duty to do so. E.g., Will v. United States, 389 U.S. 90, 95 (1967); In re Smith, 926 F.2d 1027 (11th Cir. 1991). The writ is issued in exceptional circumstances or extraordinary situations.[9] Schlagenhauf v. Holder, 379 U.S. 104, 110-11 (1964); In re Fink, M.D., 876 F.2d 84 (11th Cir. 1989); In re Smith, 926 F.2d 1027, 1030 (11th Cir. 1991); In re Paradyne Corp., 803 F.2d 604, 612 (11th Cir. 1986).

In Bauman v. United States Dist. Court, 557 F.2d 650 (9th Cir. 1977), the Court of Appeals for the Ninth Circuit developed five guidelines or factors to determine whether a class action certification proceeding will be corrected by issuing a writ of mandamus. First, the party seeking the writ must lack other adequate means, such as a right of direct appeal, to obtain the desired relief. The second related factor is whether the petitioners will be damaged or prejudiced in a way not correctable on appeal.

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[9] An issue is extraordinary if it is novel or not authorized by any rule. Pan Am World Airways, Inc. v. U.S. Dist. Ct., C.D. Cal., 523 F.2d 1073 (9th Cir. 1975).

The third guideline is whether the district court's order is clearly erroneous. The fourth factor is whether an oft-repeated error occurred or whether the district court manifested a disregard of the federal rules. The fifth factor is whether the certification order raises new and important problems or issues of first impression. Id. at 652-653. The Ninth Circuit emphasized that:

> [R]arely, if ever, will a case arise where all the guidelines point in the same direction or even where each guideline is relevant or applicable. The considerations are cumulative and proper disposition will often require a balancing of conflicting indicators.

Bauman at 655.

The Ninth Circuit's five guidelines are accepted by the Courts of Appeal for the Sixth and Tenth Circuits. See In re Bendectin Products Liability Litigation, 749 F.2d 300 (6th Cir. 1984); In re Dalton, 733 F.2d 710, 716-717 (10th Cir. 1984).

This Court adopted the Bauman analytical framework in In re Temple, 851 F.2d 1269, 1270-71 (11th Cir. 1988). Like the lower court in this case, the district court in Temple, failed to conduct a hearing before making a decision on class certification. As in this case, the district court also failed to notify the petitioners that the court was going to rule on whether the case should proceed as a class action. Because the lower court failed to hold a hearing, this Court rejected the district court's speculative finding that there existed a limited fund. The Court explained:

> The Court's failure to notify petitioners of the certification hearing denied them due process.
>
> * * *

> The non-adversarial nature of the proceeding below almost certainly led to the premature and speculative finding that a limited fund existed. . . . Without a finding as to the net worth of the defendants, it is difficult to see how the fact of a limited fund could have been established. . . . Had Raymark's motion been contested, such a salient fact would most certainly have been addressed.

Temple at 1272.

The Court of Appeals remedied the error by issuing a writ of mandamus vacating the court's order. Temple at 1272.

Temple squarely applies to this case. The errors committed by the district court in Temple are identical to the errors committed by the district court in this case. Both courts denied the petitioners due process by failing to notify them of the class certification proceedings. Both courts failed to conduct an evidentiary or adversarial proceeding. Both courts made a speculative conclusion. Temple dictates that mandamus be issued vacating the lower court's order and ordering a class certification hearing.[10]

---

[10] Application for the five guidelines enumerated in Bauman and accepted by the Court of Appeals for the 11th, 10th and 6th Circuit also leads to the same result. The petitioners have no other remedy. They cannot appeal the certification order under 28 U.S.C. § 1291 or 1292. Temple at 1270; Green v. Occidental Petroleum Corp., 541 F.2d 1335 (9th Cir. 1975). The district court's failure to hold the hearing and make findings was clearly erroneous. Temple, supra; see Dalton, supra (failure to follow Rule 23 criteria is clearly erroneous). This court's prior decisions in Morrison, supra, and Temple, supra illustrate that the failure to hold a class certification hearing is an oft-repeated error. Moreover, the court's failure to consider the criteria set forth in Rule 23 shows the court's failure to abide by the Federal Rules of Civil

See also, In re Bendectin Products Liability Litigation, 749 F.2d 300, 306 (6th Cir. 1984) (class order vacated where the petitioners were given no opportunity to dispute the unsupported finding adopted by the district court); A.H. Smith Sand & Gravel Co., v. Dept. of Water Resources, 313 A.2d 820, 826 (Md. App. 1974) (writ of mandamus may be issued to compel a hearing); Burnett v. Superior Court of Orange County, 528 P.2d 372 (Cal. 1974) (writ of mandamus proper to compel court to hear a motion); MAI Equipment Corp. v. Brooke, Mayo & Derrick, 263 So.2d 419, 420 (La. App. 1972) (the remedy for a refusal to file reasons for a judgment after a request to do so is an application for writ of mandamus); Pan Am World Airways, Inc. v. U.S. Dist. Ct., C.D. Cal., 523 F.2d 1073 (9th Cir. 1975) (inappropriate notice); McDonnell Douglas Aircraft Corp. v. United States District Court, 523 F.2d 1083 (9th Cir. 1975) (clearly erroneous certification decision corrected by mandamus); Green v. Occidental Petroleum Corp., 541 F.2d 1335, 1340 (9th Cir. 1975) (mandamus issued to correct erroneous application of the criteria set forth in Rule 23(b)(1)); Katz v. Carte Blanche Corp., 496 F.2d 746, 752 (3d Cir. 1973) (certification order may be reviewed by mandamus if the district court has acted without appropriate procedural safeguards).

Procedure. By effectively allowing only one national class, the lower court created important problems of competing claims and relief. This is one of the rare cases when all the guidelines are relevant and point toward granting mandamus. See Bauman, supra.

WHEREFORE, the petitioners pray that a writ of mandamus be issued by this Court to the Honorable Sam C. Pointer vacating his Order Denying Class Action Certification and directing the Court to hold an evidentiary hearing on the petitioners' Motion for Class Action Certification, and to make appropriate findings as a result from the hearing process.

VIII.

EXHIBITS

The exhibits attached to this application are: 1) Order Denying Class Action, July 12, 1993; 2) Petitioners' Motion and Memorandum in Support of Class Certification of Counts XII, XIII and XIV, October 28, 1992; 3) Order Certifying Class Certification and Order Confirming and Amending Class Certification in the Dante v. Dow Corning, et al. Case, February 14, 1992; 4) Robert J. DeBry Letter to Honorable Samuel C. Pointer Requesting a Hearing on Motion, October 30, 1992; 4) Transcript of Proceedings, January 2, 1993; 5) Robert J. DeBry Letter to Honorable Samuel C. Pointer Requesting a Hearing on Motion, April 29, 1993; 6) Order Denying Class Certification, May 25, 1993; 7) Petitioners' Motion that Findings of Fact and Conclusions of Law be Entered, June 22, 1993; and 8) Albrecht Second Amended Complaint, September 10, 1993.

DATED this 11 day of February, 1994.

ROBERT J. DEBRY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION MDL 926	)	Master File No. CV-92-P-10000-S
This Agreement relates to: ALL ACTIONS.	)	
HEIDI LINDSEY, et al, on behalf of themselves and all others similarly situatated, Plaintiffs, v. DOW CORNING CORPORATION, et al. Defendants.	)	Case No. CV-94-P-11558-S Honorable Sam C. Pointer, Jr.

BREAST IMPLANT LITIGATION
SETTLEMENT AGREEMENT

constitute or be deemed to constitute a waiver by Defendants or Release parties of defenses based on statutes of limitations or repose with respect to any Settlement Class Member who opts out of this Agreement during the First or Second Opt Out Periods and whose claim was barred by the applicable statues of limitations or repose as of the date of execution of this Agreement.

B. Monetary Terms/Establishment Of Settlement Fund.

4. Subject to all of the conditions contained in this Agreement, and in accordance with the terms and conditions of the Funding Agreement, the Defendants shall be obligated to pay up to the aggregate Maximum Settlement Amount set forth in the Funding Agreement in consideration for this Agreement. Each Defendant's obligation to pay under this Agreement is limited to the obligations set forth in the Funding Agreement (attached hereto as Exhibit C), and set forth in the Schedules of Defendant's Payments (attached hereto as Exhibit D).

5. All monies due and owing by Defendants under this Agreement shall be paid when due under the Funding Agreement by wire transfer in to a "Settlement Fund" to be established, maintained, invested, and administered by Settlement Class Counsel under the continuing jurisdiction and supervision of the Court. The assets of the Settlement Fund shall be invested, in the discretion of Settlement Class Counsel, in a manner intended to achieve maximum earnings consistent with safety and appropriate liquidity to pay claims without undue delay. Any and all interest

and earnings of the Settlement Fund assets shall accumulate and become part of the Settlement Fund

6. Except as specifically set forth in Sections V and XIX of this Agreement and in the Funding Agreement, Defendants and Released Parties shall have no ownership or reversionary interest in the Settlement Fund. Defendants and Released Parties shall have no interest in or responsibility for allocations or distributions therefrom and do not guarantee any earnings from any portion of the Settlement Fund assets that may be invested to generate income to satisfy claims.

7. Each Defendant shall be responsible and liable only for its individual obligations under this Agreement and under the Funding Agreement. Defendants' obligations under this Agreement and the Funding Agreement are not intended to and shall not create nor be deemed to create any joint or joint and several obligation on the part of the Defendants and Released Parties.

C. **Establishment Of Designated Funds And Disease Compensation Program For The Benefit Of Settlement Class Members**

The Settlement Amounts paid by the Defendants shall be used: (1) to establish and fund the Designated Funds as specified in this Agreement; and (2) to establish and fund the Disease Compensation Program. The assets of the Designated Funds and the Disease Compensation Program shall be used for the benefit of the Settlement Class. Settlement Class Members' inability, notwithstanding reasonable efforts, as determined by the Claims

Administrator, to identify the manufacturers of their Breast Implants shall not affect their status as Eligible Claimants.

1. Designated Funds.

The Designated Funds I-V described below shall be established with an amount aggregating approximately 16.8% of the aggregate Maximum Settlement Amounts to be paid by the Signatory Defendants under the Funding Agreement. The Notice shall advise Settlement Class Members of the amounts initially allocated by Settlement Class Counsel to Funds I-V, and by the Court to Fund VI. Each Designated Fund shall be used for the purposes described below, subject to the power, as described in Section III.F. below, to reallocate the assets of the Designated Funds as necessary and appropriate to ensure fairness to Eligible Claimants, and subject to the funding requirements to Fund VI to implement the Court's orders regarding costs, fees and expenses. Except as otherwise provided, Settlement Class Members may be eligible for payments from more than one Fund and for payments from the Disease Compensation Program. Criteria for eligibility, allocation and distribution of each of the Designated Funds shall be subject to Court approval.

a. Fund I – Medical Diagnostic/Evaluation Fund.

Fund I shall be established for the purpose of paying certain Unreimbursed Costs for medical diagnoses and evaluations with respect to Included Breast Implant Related medica problems on an ongoing basis, and to provide information for the benefit of Claimants. Recipients of payments from Fund I shall assign their

rights of reimbursement against third parties to the Settlement Fund, which would be entitled to seek reimbursement as assignee. Third parties shall not be entitled to seek reimbursement from this Fund.

All Eligible Claimants who are living Breast Implant Recipients may make application for payment of or reimbursement for medical evaluations and diagnoses pursuant to guidelines and payment schedules to be determined by Settlement Class Counsel and approved by the Court. Settlement Class Counsel may, in their discretion, establish one or more experienced practitioners or researchers to serve as medical evaluation advisors who may provide advice and assistance for the benefit of the evaluating doctors and their patients. Costs associated with the establishment and maintenance of such advisors shall be paid from the assets of Fund I.

b. **Fund II - Explantation Fund.**

Fund II shall be established to pay or reimburse Eligible Claimants for certain Unreimbursed Costs associated with explantation of Breast Implants and related necessary surgery. Guidelines for eligibility for and amounts of individual payments to Eligible Claimants from Fund II shall be determined by Settlement Class Counsel and approved by the Court. Claimants shall not be reimbursed for the cost of any surgery performed to implant any Breast Implants after June 1, 1993, or for the removal of any Breast Implants implanted after June 1, 1993.

c. Fund III - Rupture Fund.

Fund III shall be established to provide payment to Eligible Claimants who have had one or more ruptures of an Included Breast Implant and who are not Eligible Current Claimants under the Disease Compensation Program. Guidelines for eligibility for compensation from Fund III, and the schedule of payments to rupture claimants, will be determined by Settlement Class Counsel and approved by the Court.

d. Fund IV – Breast Implant Recipient Compensation Fund.

Fund IV shall be established to provide payment to Eligible Claimants who are not Eligible Current Claimants under the Disease Compensation Program, and who do not qualify for a payment under Fund III (Rupture Fund). Claimants who meet these criteria are eligible to receive a share of this fund as determined by Settlement Class Counsel and approved by the Court.

e. Fund V - Reserve Fund.

Fund V shall be established as a Reserve Fund to be used as Settlement Class Counsel deems necessary and appropriate under this Agreement for the benefit of Settlement Class Members, subject to Court approval.

f. Fund VI - Settlement Class Costs, Expenses and Fees.

Fund VI shall be established by Court order to fund all costs of settlement notice and claims administration, and to pay such reimbursement of costs and expenses and awards of fees as the

Court may approve to counsel who represent individual Settlement class Members and/or the Settlement Class. Fund VI shall be funded, as directed by the Court, by a specified percentage of the aggregate Settlement Amount and shall not constitute an additional obligation of Defendants. All payments of costs and expenses and awards of attorneys' fees incurred in connection with settlement Class Members' rights and claims under this Agreement shall be subject to Court Approval and, if approved, shall be paid from Fund VI. Payments to Settlement Class Members from the other Designated funds and from the Disease Compensation Program shall be net payments to Eligible Claimants for the purpose of preserving payment parity, such that similarly situated Eligible Claimants shall receive similar amounts without regard to their individual fee agreements with counsel, if any. Settlement Class Members shall have no other attorneys' fees, expenses or cost obligations with respect to benefits under this Agreement and payments form any Designated Fund or from the Disease Compensation Program.

g. **Adjustments in the Event of Withdrawal or Final Default.**

In the event of the withdrawal or Final Default of a Defendant, amounts allocated to the above Funds shall be adjusted in accordance with the provisions of Sections V and XIII of this Agreement.

2. Disease Compensation Program.

The Disease Compensation Program shall be a program under which Eligible Claimants who satisfy the diagnostic criteria set forth in the Disease Definitions shall be entitled to receive payment in accordance with the Disease Compensation Schedule, subject to the procedures and adjustments to the Disease Compensation Schedule prescribed below. The Disease Compensation Program shall be maintained for the Initial Claims Period and a thirty (30) year ongoing period ("the Ongoing Disease Compensation Program").

a. Compensation for Eligible Current Claimants Under the Disease Compensation Program.

(1) Limitation on Aggregate Payment for Current Claimants.

The Initial Payment shall be paid as set forth in the Funding Agreement (Exhibit C hereto) and Schedules of Defendants' Payments (Exhibit D hereto) to fund the Disease Compensation Program for Eligible Current Claimants. If the total dollar amount of Eligible current Claims paid under the Disease Compensation Program is less than the Initial Payment, the unused portion of the Initial Payment shall be applied to pay Eligible Ongoing claims under the Disease Compensation Program, if and when needed as provided in Section III.C.2.b(2)(c) of this Agreement. Application of the unused portion of the Initial Payment to pay Eligible Ongoing Claims shall not reduce the Settlement Amount.

(2) Determination of Payment Amounts.

Each Eligible Current Claimant shall receive a payment as prescribed for the appropriate disease, level of severity, and age category on the Disease Compensation Schedule (Exhibit F hereto). This amount may be adjusted as provided below. Additionally, a percentage to be determined by the Court may be deducted for purposes of funding Fund VI.

EXHIBIT "D"
DOW CORNING CORPORATION FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$42.50	$42.50
YEAR 1	$275.00	$317.50
YEAR 2	$275.00	$592.50
YEAR 3	$275.00	$867.50
YEAR 4	$51.17	$918.67
YEAR 5	$51.17	$969.84
YEAR 6	$51.17	$1,021.01
YEAR 7	$51.17	$1,072.18
YEAR 8	$51.17	$1,123.35
YEAR 9	$51.17	$1,174.52
YEAR 10	$51.17	$1,225.69
YEAR 11	$51.17	$1,276.86
YEAR 12	$51.17	$1,328.03
YEAR 13	$51.17	$1,379.20
YEAR 14	$51.17	$1,430.37
YEAR 15	$51.17	$1,481.54
YEAR 16	$51.17	$1,532.71
YEAR 17	$38.38	$1,571.09
YEAR 18	$38.38	$1,609.47

YEAR 19	$38.38	$1,647.85
YEAR 20	$38.38	$1,686.23
YEAR 21	$38.38	$1,724.61
YEAR 22	$38.38	$1,762.99
YEAR 23	$38.38	$1,801.37
YEAR 24	$38.38	$1,839.75
YEAR 25	$25.57	$1,865.32
YEAR 26	$25.57	$1,890.89
YEAR 27	$25.57	$1,916.46
YEAR 28	$25.57	$1,942.03
YEAR 29	$25.57	$1,967.60
YEAR 30	$25.57	$1,993.17
YEAR 31	$25.57	$2,018.74
TOTALS	$2,018.74	$2,018.74
MAXIMUM SETTLEMENT AMOUNT		$2,018.74

EXHIBIT "D"
BAXTER HEALTHCARE CORPORATION FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$11.70	$11.70
YEAR 1	$152.10	$163.80
YEAR 2	$64.35	$228.15
YEAR 3	$64.35	$292.50
YEAR 4	$11.70	$304.20
YEAR 5	$11.70	$315.90
YEAR 6	$11.70	$327.60
YEAR 7	$11.70	$339.30
YEAR 8	$11.70	$351.00
YEAR 9	$11.70	$362.70
YEAR 10	$11.70	$374.40
YEAR 11	$11.70	$386.10
YEAR 12	$11.70	$397.80
YEAR 13	$11.70	$409.50
YEAR 14	$11.70	$421.20
YEAR 15	$11.70	$432.90
YEAR 16	$11.70	$444.60
YEAR 17	$8.78	$453.38
YEAR 18	$8.78	$462.16

YEAR 19	$8.78	$470.94
YEAR 20	$8.78	$479.72
YEAR 21	$8.78	$488.50
YEAR 22	$8.78	$497.28
YEAR 23	$8.78	$506.06
YEAR 24	$8.78	$514.84
YEAR 25	$5.85	$520.69
YEAR 26	$5.85	$526.54
YEAR 27	$5.85	$532.39
YEAR 28	$5.85	$538.24
YEAR 29	$5.85	$544.09
YEAR 30	$5.85	$549.94
YEAR 31	$5.85	$555.79
TOTALS	$555.79	$555.79
MAXIMUM SETTLEMENT AMOUNT		$555.79

EXHIBIT "D"
MEDICAL ENGINEERING CORPORATION AND BRISTOL-MYERS SQUIBB COMPANY FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$24.30	$24.30
YEAR 1	$315.90	$340.20
YEAR 2	$133.65	$473.85
YEAR 3	$133.65	$607.50
YEAR 4	$24.30	$631.80
YEAR 5	$24.30	$656.10
YEAR 6	$24.30	$680.40
YEAR 7	$24.30	$704.70
YEAR 8	$24.30	$729.00
YEAR 9	$24.30	$753.30
YEAR 10	$24.30	$777.60
YEAR 11	$24.30	$801.90
YEAR 12	$24.30	$826.20
YEAR 13	$24.30	$850.50
YEAR 14	$24.30	$874.80
YEAR 15	$24.30	$899.10
YEAR 16	$24.30	$923.40
YEAR 17	$18.23	$941.63

YEAR 18	$18.23	$959.86
YEAR 19	$18.23	$978.09
YEAR 20	$18.23	$996.32
YEAR 21	$18.23	$1,014.55
YEAR 22	$18.23	$1,032.78
YEAR 23	$18.23	$1,051.01
YEAR 24	$18.23	$1,069.24
YEAR 25	$12.15	$1,081.39
YEAR 26	$12.15	$1,093.54
YEAR 27	$12.15	$1,105.69
YEAR 28	$12.15	$1,117.84
YEAR 29	$12.15	$1,129.99
YEAR 30	$12.15	$1,142.14
YEAR 31	$12.15	$1,154.29
TOTALS	$1,154.29	$1,154.29
MAXIMUM SETTLEMENT AMOUNT		$1,154.29

S. Supreme Court, U.S.
FILED
JUL 13 1994
OFFICE OF THE CLERK

No. 93-2052

In The

Supreme Court of the United States

October Term, 1994

CONNIE ALBRECHT, ET AL.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE FOR THE NORTHERN DISTRICT OF ALABAMA HONORABLE SAM C. POINTER, JR., PRESIDING AND McGHAN MEDICAL CORPORATION, ET AL.,

Respondents.

Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

BRIEF OF RESPONDENT DOW CORNING CORPORATION IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

FRANK C. WOODSIDE, III
Counsel of Record
JOHN E. SCHLOSSER
MARY-JO MIDDELHOFF
JEFFREY R. SCHAEFER
DINSMORE & SHOHL
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8200

RAY R. CHRISTENSEN
GAINER M. WALDBILLIG
CHRISTENSEN, JENSEN & POWELL
175 South West Temple
#510
Salt Lake City, Utah 84101
(801) 355-3431

Counsel for Respondent, Dow Corning Corporation

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

BEST AVAILABLE COPY

CORPORATE DISCLOSURE STATEMENT

The following corporations are affiliated with Respondent Dow Corning Corporation and are disclosed in accordance with United States Supreme Court Rule 29.1: The Dow Chemical Company; Corning Incorporated; Dow Corning Krafft S.A.; Dow Corning STI S.A.; Devonshire Underwriters Ltd.; Dow Corning S.A.; Dow Corning Toray Silicone; Dow Corning de Mexico S.A. de C.V.; Dow Corning Limited; Dow Corning Singapore Pte. Ltd.; Dow Corning de Venezuela S.A.; Dow Corning Malaysia Sdn. Bhd.; Dow Corning Chile S.A.; Dow Corning (Thailand) Limited; Dow Corning STI Limited; Dow Corning Taiwan Inc.; Dow Corning Construction S.A.; Dow Corning Do Brasil Limitada; Dow Corning Foreign Sales Corporation; Dow Corning Investment S.A.; Dow Corning Argentina S.A.; Dow Corning Coordination Center S.A.; Dow Corning Hansil, Ltd.; Dow Corning France, S.A.; Dow Corning de Columbia S.A.; Hemlock Semiconductor Corporation; Lucky-DC Silicone Co., Ltd.; SDC Coatings Inc.; Siltech Limited; and Universal Silicones and Lubricants Private Ltd.

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COUNTER-STATEMENT OF THE CASE

This case is one of many filed in the state and federal courts by silicone breast implant recipients. Beginning in June 1992, the federal breast implant cases were transferred pursuant to 28 U.S.C. §1407 to the Northern District of Alabama, Southern Division, and consolidated for pretrial proceedings before District Judge Sam C. Pointer, Jr. *See In re: Silicone Gel Breast Implant Products Liability Litigation, No. 926*, 793 F.Supp. 1098 (Jud. Pan. Mult. Lit. 1992).

Since that time, Judge Pointer has taken an active role in all phases of the litigation. He issued two exhaustive case management orders which included orders appointing National Liaison Co-Counsel for Plaintiffs. Res.App. at pp. A-65 and A-69.[1] Among the duties of such liaison counsel was to accept service of all orders, motions, briefs and other documents which would otherwise have had to be served on the many individual Plaintiffs' counsel.[2]

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[1] Respondent will cite to Petitioners' Appendix as well as to its own. Respondent's Appendix begins with page A-65.

[2] Likewise, Judge Pointer appointed a Plaintiffs' National Steering Committee to coordinate discovery and other pre-trial proceedings on behalf of Plaintiffs. Judge Pointer has directed the conduct of consolidated and comprehensive discovery, overseen the maintenance of a joint federal-state document depository and ordered and approved the drafting of master pleadings tailored to this litigation. He has held monthly status conferences to monitor the progress of the litigation, to resolve disputes and to allow parties in attendance to be heard on many issues. As a general rule, Judge Pointer has varied the location of the status conferences to accommodate parties and counsel in other parts of the country. Moreover, it has been his practice at each conference to announce the date of the next conference in open court.

Judge Pointer has also encouraged and assisted the parties in the negotiation of a global settlement of all claims related to silicone breast implants. On April 1, 1994, a non-mandatory settlement class was conditionally certified by Judge Pointer in *Lindsey, et al. v. Dow Corning Corp., et al.*, Civil Action No. CV94-P-11558-S (N.D. AL) Res.App. at p. A-84. The *Lindsey* class includes, among others, all persons who were implanted before June 1, 1993, with silicone breast implants, whether or not they have been removed or may later be removed, with respect to any existing or future claims. A fairness hearing is scheduled to take place on August 18, 1994 to determine whether to grant final approval to the proposed Settlement Agreement as fair, adequate, and reasonable, to confirm or modify certification of the Settlement Class and to issue a Final Order and Judgment thereon. Thirty days after an order confirming and permanently certifying a class in the *Lindsey* action has become final, proposed class certification in any other federal action then pending shall be deemed as denied and class certification in the previously conditionally certified class action captioned *Dante, et al. v. Dow Corning Corp., et al.*, CV92-P-10060-S (N.D. AL)[3] shall be deemed vacated.

Petitioners filed their class action complaint in the United States District Court for the District of Utah in October 1992 and served it on Respondent Dow Corning

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[3] *Dante* was conditionally certified by Judge Carl B. Rubin in the U.S. District Court for the Southern District of Ohio, and was transferred, along with all other federal breast implant cases, to the Northern District of Alabama.

Corporation by summons dated October 29, 1992. By the time the process was received by Respondent, Petitioners had filed a motion for class certification in Utah district court. Res.App. at p. A-99. However, on October 30, 1992, while the action was still pending in Utah, Petitioners' counsel wrote to the district court in Alabama asking that it set the class certification motion for hearing in December 1992 or early January 1993. Pet.App. at p. A-15. The lawsuit had not yet been transferred to the multidistrict litigation proceedings and Judge Pointer as yet had no jurisdiction over the case.

The underlying suit appeared on Conditional Transfer Order No. 9, dated November 24, 1992. On or about December 8, 1992, the transfer of the case (and as a practical matter, the case file) from the District of Utah was effected and the district court in Alabama assumed jurisdiction over the case for all purposes, including decision on Petitioners' pending motion for class certification.

Petitioners' October 30, 1992 letter did not request an *evidentiary* hearing, nor did Petitioners make a proffer of the evidence, if any, which they intended to offer in support of their motion for class certification. Likewise, the motion itself offered no documentary evidence, by affidavit or otherwise, in support of class certification nor did it intimate any plan to supply evidence thereafter by any means. The motion also failed to provide any facts peculiar to the class members which would have provided the district court with new or different information on silicone breast implants or the women in whom they have been implanted. In fact, Petitioners' memorandum in support of their motion stated:

> Although asserting three distinctive legal theories, the factual background of this newly filed case is substantially similar with or identical to all other cases which have been consolidated to the Federal District Court in Birminghan, Alabama pursuant to MDL Order No. 926. Res.App. at pp. A-101-102.

On January 2, 1993, the district court, in a regularly scheduled status conference, denied Petitioners' motion. District Judge Pointer stated:

> To the extent that these are appropriate claims and to the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action. That is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory. Pet.App. at pp. A-13-14.

Petitioners' counsel did not attend this status conference.[4] In an April 29, 1993 letter, Petitioners' counsel again requested that the district court decide the motion for class certification. Pet.App. at p. A-17. Once again, Petitioners did *not* 1) request an *evidentiary* hearing, 2) offer any evidence or, 3) articulate additional facts to the court. They did, however, reiterate many of the arguments which they had made in their written motion.

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[4] It is common practice in MDL-926 for counsel to notify the district court of pending motions and appear at subsequent hearings for argument and ruling. Any questions by the parties regarding MDL-926 practice and procedure are and should be addressed to the respective liaison counsel.

After being notified (by Respondent) that the district court had denied the class certification motion, Petitioners again wrote to the court. Res.App. at p. A-118. Petitioners' counsel advised the court of arguments which he would have made, had he been present at the status conference. Again, he gave no indication of additional facts or evidence which he sought to bring to the court, or which would warrant an evidentiary hearing. The district court issued a written order on May 25, 1993 again denying class certification. Pet.App. at p. A-11.

On or about June 22, 1993, Petitioners filed a motion citing Rule 52, Fed. R. Civ. P., requesting the district court to enter Findings of Fact and Conclusions of Law in support of the order denying class certification. The district court granted Petitioners' motion, entering the following observation:

> The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Pet. App. at p. A-10.

On or about February 11, 1994, Petitioners filed a Petition for a Writ of Mandamus in the Court of Appeals for the Eleventh Circuit. Petitioners sought the writ 1) to compel Judge Pointer to vacate his order denying class certification, 2) to direct him to hold an evidentiary hearing on Petitioners' motion for class certification and 3) to require him to make appropriate findings of fact after the hearing. Pet.App. at p. A-28. This was the first mention of an *evidentiary* hearing, but Petitioners again made no

specific proffer or general description of the evidence which they would present at such a hearing. On or about March 11, 1994, the Eleventh Circuit denied the petition. Pet.App. at p. A-1.

Thereafter, this Petition was filed addressed to the class certification process and the role of the Nuremberg Code in U.S. law.

SUMMARY OF REASONS FOR DENYING THE WRIT

Petitioners attack the district court's order denying certification of a class arguing that the district court failed to "appreciate" the Nuremberg Code as the basic ethical standard for human experimentation. Pet. at p. 9. They ask this Court to find the Nuremberg Code to be part of due process constitutional law or federal common law. This issue may not be decided by the Supreme Court because the sufficiency of Petitioners' Nuremberg Code cause of action was not adjudicated in the lower courts. Therefore, the issue is not ripe for *certiorari*.

Petitioners also assail the court of appeals' refusal to issue a writ of mandamus vacating the district court's order of denial of class certification. This Court has clearly stated that a writ of mandamus is proper only in the extraordinary circumstance in which it is clear and indisputable that an abuse of discretion rising to the level of judicial usurpation of power has occurred and must be remedied. Petitioners have failed to assert that such an abuse took place in this case and furthermore, they have

failed to explain how a favorable resolution of the questions which they have broached to this Court would ultimately change the outcome in the district court.

REASONS FOR DENYING THE WRIT

I. THE LOWER COURTS HAVE NOT REACHED OR ADJUDICATED THE SUFFICIENCY OF PETITIONERS' CAUSE OF ACTION BASED ON THE NUREMBERG CODE

Petitioners sought to certify a plaintiff class to press a claim based on the Nuremberg Code which Petitioners characterize as a "common law ethical standard for human experimentation." Pet. at p. 3. They ask this Court to find that the Nuremberg Code is part of "due process constitutional law or federal common law." Pet. at p. 3. There is no legal authority whatsoever for the proposition that the Nuremberg Code creates a cause of action or, as asserted by Petitioners, has "been considered to be common law" by courts. Pet. at p. 13, n.11.[5] There has been no

[5] Petitioners cite *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. App. 1969) as a case in which the Nuremberg Code was found to be a part of the common law. This case does not even deal with human experimentation, but rather with the issue whether a court of equity has the power to allow a kidney to be removed from an incompetent donor for transplant into his severely ill brother. The *Strunk* court *does not even mention* the Nuremberg Code. Likewise, Petitioners' reliance on *Pierce v. Ortho Pharmaceutical Corp.*, 84 N.J. 58, 417 A.2d 505 (1980) is misplaced. That case asked whether a physician-researcher employee had a cause of action for wrongful discharge where she perceived that

ruling at any stage, in any court, pro or con, on this point in this action or the underlying action.

In Count XIII of their Complaint and the Amendments thereto, Petitioners pleaded the purported elements of a claim based on the Nuremberg Code. They sought class certification against Respondent Dow Corning Corporation, only.

The district court denied class certification, without ruling on the Nuremberg Code claim. Its Findings of Fact, dated July 12, 1993, held that the claims by Petitioners on behalf of all women "without bodily injuries" could be dealt with more efficiently in preexisting litigation rather than through a new separate class action for the Nuremberg Code claims. Pet.App. at p. A-10. The court cautioned that its denial of class certification was, in no way, a ruling on the merits or sufficiency of the Nuremberg Code claim, either for any plaintiff class or individual. Pet.App. at p. A-14. Consequently, Petitioners' assertion that the district court "ignored" the Nuremberg Code is

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her research activities would cause her to violate ethics expressed in the Hippocratic Oath. Only the dissent raises the Nuremberg Code as "clear mandate of public policy." *Id.* at 516-17.

The courts in *Kamowitz v. Michigan Department of Mental Health*, Civ. No. 73-19434-AW (Mich Cir. Ct. 1973), and *Whitlock v. Duke University*, 637 F.Supp.1463 (M.D.N.C. 1986) simply looked to the Nuremberg Code for guidance in the absence of statutory or other authority on informed consent in the context of human experimentation. Neither court adopted the Code as binding precedent to govern cases of experimentation with human subjects, let alone a product liability claim against a non-physician.

false. Denial of class certification by the district court was not a ruling on the substantive merits of any claim.

Neither did the court of appeals adjudicate Petitioners' Nuremberg Code claims. Petitioners' mandamus petition was addressed solely to the process by which the district court denied class certification, and did not reach the merits of the case. Even Petitioners did not ask the court of appeals to recognize a federal cause of action based on the Nuremberg Code because it was clear that the district court had not yet refused to do so. Therefore, there is no decision by any court below, presented here for review by the Supreme Court, on the sufficiency of this novel and imaginative theory. In fact, it is not even possible for this Court to render a decision on Petitioners' Nuremberg Code question as the issue has not been litigated by the parties, or disposed of by any court at the trial level.

To date, Petitioners' Nuremberg Code claims remain pending. Each petitioner who does not choose to participate in the "global" settlement described *supra* is free to pursue her Nuremberg Code claim individually against Respondent Dow Corning Corporation. At that time, the viability of a cause of action based on the Nuremberg Code may well be challenged by Respondent. At the very least, unless and until the district court first rules (adversely or favorably to Petitioners) on this issue and the court of appeals has had opportunity to review that ruling, it is not ripe for *certiorari*. Obviously, the issue may never become ripe in this case. Thus, the Petition should be denied.

II. A WRIT OF MANDAMUS TO A DISTRICT COURT JUDGE IS PROPER ONLY WHERE IT IS CLEARLY AND INDISPUTABLY SHOWN THAT AN ABUSE OF DISCRETION CONSTITUTING JUDICIAL USURPATION OF POWER MUST BE REMEDIED.

This Court has described mandamus against a United States district judge as a drastic remedy. *Kerr v. United States District Court for the Northern District of California*, 426 U.S. 394, 402 (1976). Its use is to be reserved for the exceptional circumstance constituting "judicial usurpation of power." *Will v. United States*, 389 U.S. 90, 95 (1967). The seminal case cited in *Will* also cautions that "mere error in the exercise of conceded judicial power" is not enough. *DeBeers Consol. Mines v. United States*, 325 U.S. 212, 217 (1944). *At best*, Petitioners' petition for mandamus stated an allegation of a single isolated instance of "mere error" in the denial of class certification. The writ was properly denied.

A. Petitioners do not allege a clear and indisputable right to issuance of the writ.

Due to the coercive nature of any writ of mandamus issued against a federal district judge, a party seeking the writ must satisfy a very high standard of proof. The right to mandamus must be clear and indisputable. *Mallard v. United States District Court for the Southern District of Iowa*, 490 U.S. 296, 309 (1989), quoting *Bankers Life and Casualty Co. v. Holland*, 346 U.S. 379, 384 (1953), quoting *United States v. Duell*, 172 U.S. 576, 582 (1899). Further, this Court has recognized that the issuance of mandamus is within

the discretion of the court being petitioned for the writ. *Kerr v. United States District Court*, 426 U.S. at 403.

Thus, a party seeking review of the denial of mandamus must, at the least, allege an abuse of discretion and the disregard of a clear and indisputable right to the writ. However, Petitioners allege no abuse of discretion by the court of appeals, rather phrasing their arguments as if they were appealing from the district court's order in the underlying suit. Petitioners also fail to allege a clear and indisputable right to the writ or that the same was shown to the court of appeals. Instead, Petitioners ask this Court to resolve several issues of law relating to a highly discretionary device (mandamus) without explaining how resolving those issues could ultimately change the outcome on remand.

B. This case presents no controversy on the right of circuit courts of appeals to issue mandamus on class certification issues.

Petitioners' claim that this case "presents . . . an opportunity to establish uniform criteria for mandamus review," Pet. at p. 22, is simply inaccurate. Nothing suggests that the court of appeals doubted its authority – in a proper case – to issue mandamus concerning class certification. Petitioner concedes that the Eleventh Circuit recognizes its authority in this regard. *See In re Temple*, 851 F.2d 1269 (11th Cir. 1988), cited at page 24 in the Petition. Petitioners, in positing a conflict among the circuits on whether mandamus is available on class certification issues, erect a straw man. No party before this

Court in this case will argue that such authority is lacking. Respondents' position on class certification has already been sustained without the necessity that they even take a position on whether the circuit court had authority to issue mandamus. Neither the district court nor this Respondent will gratuitously assault the precedent of the Eleventh Circuit on an issue on which *Respondents have already prevailed.*

This is not a case in which the availability of mandamus is an active controversy. Even if it were, Petitioners have neither shown nor even alleged how any standard which they will urge this Court to adopt will procure the writ for them on remand. Likewise, Petitioners never argued for any change in the law of mandamus in the Eleventh Circuit, and therefore should not be permitted to do so here.

C. Petitioners have shown no reason why this court should involve itself in multidistrict litigation in an area within the district court's discretion.

Mandamus actions against district judges make judges unwilling participants in litigation and may leave their defense in the hands of parties to the underlying litigation. *Ex Parte Fahey,* 332 U.S. 258, 260 (1947). The potential for misuse of a mandamus action to obtain an otherwise unavailable interlocutory appeal has also been recognized. *Bankers Life & Cas. Co. v. Holland,* 346 U.S. 379, 382-83 (1953).

Mandamus actions against federal judges have been limited to circumstances in which a judge has committed

a degree of abuse of discretion which exceeds "ordinary" abuse. *In re Catawba Indian Tribe*, 973 F.2d 1133, 1137 (4th Cir. 1992). This "high abuse" has long been characterized as "judicial usurpation of power." *See Will v. United States*, 389 U.S. 90, 95 (1967). Where a ruling of law is made in the course of a judge's jurisdiction on an issue properly before the judge, that ruling, even if erroneous, is not an abuse of power warranting mandamus. *See Bankers Life* at 382-83. Similarly, denial of class certification in this case constituted no abuse of power.

Petitioners claim that no "hearing" was held and no "meaningful" findings of fact and conclusions of law were issued by Judge Pointer.[6] The motion for class certification was discussed at a regularly scheduled MDL-926 status conference which Petitioners' counsel did not attend. This was a "hearing" in keeping with normal practice in this MDL proceeding. The class certification question was decided on the basis of the Petitioners' memorandum, and reconsidered in response to Petitioners' written protests. Only in the court of appeals was an "evidentiary hearing" demanded. Never, to this day, have Petitioners hinted what evidence they planned to offer on a motion on which they had, so far, offered none. Ultimately, a written order was issued stating the court's conclusions in light of Petitioners' arguments for reconsideration.

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[6] Rule 52(a) Fed.R.Civ.P., by its terms, makes findings of fact and conclusions of law "unnecessary" for a ruling on a class certification motion. The rule obviates what Petitioners maintain it requires.

The entire objective of multi-district litigation is the efficiency associated with having the cases managed by a single judge familiar with all aspects of a complex litigation. The Petitioners may properly seek review only of the judgment of the court of appeals, and not of the interlocutory order of Judge Pointer, which is not, and has not yet become, appealable.

CONCLUSION

For the foregoing reasons, the Petition should be denied.

Respectfully submitted,

FRANK C. WOODSIDE, III
Counsel of Record
JOHN E. SCHLOSSER
MARY-JO MIDDELHOFF
JEFFREY R. SCHAEFER
DINSMORE & SHOHL
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8200

RAY R. CHRISTENSEN
GAINER M. WALDBILLIG
CHRISTENSEN, JENSEN & POWELL
175 South West Temple #510
Salt Lake City, Utah 84101
(801) 355-3431

Attorneys for Respondent,
Dow Corning Corporation

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File
	)	No. CV 92-P-10000-S
SILICONE GEL BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION (MDL-926)	)	This Document Relates to: All Cases

ORDER NO. 1
(Initial Case Management Order)

(Filed June 26, 1992)

It appearing that the cases listed on Attachment A, which have been transferred to this court under 28 U.S.C. § 1407, merit special attention as complex litigation, the court ORDERS:

1. **Initial Conference.** The court will conduct a conference under Fed. R. Civ. P. 16 and 26(f) at 9:00 a.m., Monday, July 20, 1992, in Courtroom 8 at the Hugo L. Black Courthouse, Birmingham, Alabama.

(a) **Attendance.** To minimize costs and facilitate a manageable conference, parties are not required to attend the conference, and parties with similar interests are expected to agree to the extent practicable on a single attorney to act on their joint behalf at the conference. A party will not, by designating an attorney to represent its interests at the conference, be precluded from other representation during the litigation; and attendance at the conference will not waive objections to jurisdiction, venue, or service.

(1) **Service List.** This order is being mailed to the persons shown on Attachment B, which has been prepared from the list of counsel making appearances with the Judicial Panel on Multidistrict Litigation. Counsel on this list are requested to forward a copy of the order to other attorneys who should be notified of the conference. A corrected service list will be prepared after the conference.

(2) **Other Participants.** Counsel for persons or entities who are not named as parties in the cases initially transferred by the JPMDL but may be later joined as parties or are parties in related litigation pending in other federal and state courts are welcome to attend the conference.

(b) **Purposes; Agenda.** The conference will be held for the purposes specified in Fed. R. Civ. P. 16(a), 16(b), 16(c) and 26(f). A tentative agenda is appended as Attachment C.

(c) **Preparations for Conference.**

(1) **Procedures for Complex Litigation.** Counsel will familiarize themselves with the *Manual for Complex Litigation, Second,* and be prepared at the conference to suggest procedures that will facilitate the expeditious, economical, and just resolution of this litigation.

(2) **Meeting of Counsel.** Before the conference, counsel for the plaintiffs and counsel for the defendants shall separately confer and seek consensus to the extent possible with respect to the items on the agenda, including a proposed discovery

plan under Rule 26(f), methods to obtain discovery of expert testimony, and the timing for consideration of motions and for resolution of controversies regarding maintenance of one or more cases as class actions.

(d) **Preliminary Reports.** Counsel will submit to the undersigned by July 14, 1992, a *brief* written report indicating their preliminary understanding of the facts involved in the litigation and what they expect to be the critical factual and legal issues. These statements will not be filed with the Clerk, will not be binding, will not waive other claims or defenses, and may not be offered in evidence against a party in later proceedings. To the extent feasible, the statements of parties with similar interests should be consolidated and submitted as a single document.

(1) **List of Affiliated Companies and Counsel.** To assist the court and other counsel in identifying any problems of recusal or disqualification, the reports should include as an appendix a list of all companies affiliated with the parties and of all counsel associated in the litigation.

(2) **List of Pending Motions.** The reports should briefly summarize the nature of pending motions.

(3) **State Court Litigation.** The reports should briefly summarize, to the extent known, the nature and status of similar litigation pending in state courts.

(4) **Lead and Liaison Counsel; Steering Committee.** Attorneys interested in

serving as Lead, Liaison, or Coordinating Counsel or on a committee of counsel to assist in coordination and management of the litigation shall also submit information outlining how and at what rates they will expect to be compensated or reimbursed for services rendered to other parties and counsel and what agreements or commitments they have made respecting the role and responsibility of other attorneys in conducting pretrial proceedings, discovery, and trial.

2. **Interim Measures.** Until otherwise ordered by the court:

(a) **Admission of Counsel.** Attorneys admitted to practice and in good standing in any United States District Court are hereby permitted to appear pro hac [sic] vice in this litigation, without need for any other motion, order, or payment of fee. Association of local counsel is not required.

(b) **Pretrial consolidation.** The cases listed on Attachment A are consolidated for pretrial proceedings. This order does not constitute a determination that these actions should be consolidated for trial, nor does it have the effect of making any entity a party to an action in which it has not been joined and served in accordance with the Federal Rules of Civil Procedure.

(1) **Master Docket and File.** The Clerk will maintain a master docket and case file under the style "In re Silicone Gel Breast Implants Product Litigation (MDL-926)" as master file number CV 92-P-10000-S. All

orders, pleadings, motions, and other documents will, when filed and docketed in the master case file, be deemed filed and docketed in each individual case to the extent applicable.

(2) **Captions; Separate Filing.** Orders, pleadings, motions and other documents will bear a caption similar to that of this order. If generally applicable to all consolidated actions, they shall include in the caption the notation that they relate to "All Cases" and shall be filed and docketed only in the master file. Documents intended to apply only to particular cases will indicate in their caption the case number of the case(s) to which they apply, and extra copies shall be provided to the Clerk to facilitate filing and docketing both in the master case file and in the specified individual case files.

(c) **Pleadings.** Each defendant is granted an extension of time for responding by motion or answer to the complaints until a date to be set at the conference.

(d) **Motions.**

(1) No motion shall be filed under Rule 11 or Rule 56 without leave of court.

(2) No motion (other than under Rule 12) shall be filed unless it includes a certification that the movant has conferred with opposing parties and made a good faith effort to resolve the matter without court action.

(3) **Preservation of Records.** Each party shall preserve all documents and

other records containing information potentially relevant to the subject matter of this litigation. Subject to further order of the court, parties may continue routine erasures of computerized data pursuant to existing programs, but they shall (1) immediately notify opposing counsel about such programs and (2) preserve any printouts of such data. Requests for relief from this directive will receive prompt attention from the court.

(f) **Discovery.**

(1) **Non-filing of Discovery Documents.** Pursuant to Fed. R. Civ. P. 5(d), discovery requests and responses will not be filed with the court except when specifically so ordered by the court or to the extent needed in connection with a motion.

(2) **Pending and New Discovery.** Pending the conference, all outstanding discovery proceedings are stayed and no further discovery shall be initiated. This directive does not (A) preclude informal discovery regarding the identification and location of relevant documents and witnesses; (B) preclude parties from stipulating to the conduct of a deposition that has already been scheduled; (C) prevent a party from voluntarily responding to an outstanding discovery request under Rule 33, 34, or 36; or (D) authorize a party to suspend its efforts in gathering information needed to respond to a request under Rule 33, 34, or 36. Relief from this stay may be granted for good cause shown, such as the ill health of a proposed deponent.

(3) **Deadlines.** Orders issued by transferor courts imposing dates for initiation or completion of discovery are vacated.

(g) **Magistrate Judge.** The undersigned expects to handle personally, to the extent practical, all matters requiring or deserving judicial attention, including discovery disputes. In the absence or unavailability of the undersigned, matters requiring immediate judicial attention are automatically referred, without need for special order, to Magistrate Judge Elizabeth Todd Campbell for disposition or report and recommendation as may be appropriate.

(h) **Later Cases.** The interim orders contained in this paragraph 2, including pretrial consolidation, shall apply automatically to actions later instituted in, removed to, or transferred to this court (including cases transferred for pretrial purposes under 28 U.S.C. § 1407) that involve claims relating to silicone gel breast implants.

This the 26th day of June, 1992.

/s/ Sam C. Pointer, Jr.
United States District Judge

Attachments:
A– List of cases
B – Service list
C – Tentative agenda

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File No.
	)	CV 92-P-10000-S
SILICONE GEL BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION (MDL-926)	)	(This Document Relates To: All Cases)

Order No. 5
(Revised Case Management Order)

(Filed Sept. 15, 1992)

On July 20-21, 1992, and August 21, 1992, conferences were held pursuant to Rule 16 in Birmingham, Alabama. This order is entered as a result of discussions at those conferences. It supplements and, to the extent inconsistent, supersedes all prior orders and applies to all cases that have been or are subsequently filed in, removed to, or transferred to this court as part of the Silicone Gel Breast Implant Litigation, including any cases involving other implant product liability claims considered suitable for inclusion in this litigation. A copy of Exhibit A to this Order will be filed and docketed in each such case.

Caution: The terms of this order automatically apply to cases transferred to the Northern District of Alabama under 28 U.S.C. § 1407 once the transfer order from the JPMDL has been filed in this court. Until that time (including the time a conditional transfer order is pending), the terms of this order do not apply to a case filed in another district unless that court so orders.

1. **Admission of Counsel.** Attorneys admitted to practice and in good standing in any United States District Court are hereby permitted to appear pro hac [sic] vice in this litigation without need for any other motion, order, or payment of fee. Association of local counsel is not required.

2. **Pretrial Consolidation.** All cases in this litigation are consolidated for pretrial purposes. This is not a determination that any of these actions should be consolidated for trial, and does not have the effect of making any entity a party to an action in which it has not been named and served.

3. **Filing of Papers with Court.** The purpose of the following instructions is to reduce the time and expense of duplicate filings of documents through use of a master case file, while at the same time not congesting the master case with miscellaneous pleadings and orders that are of interest only to the parties directly affected by them. It is not intended that a party would lose any rights based on a failure to follow these instructions.

(a) **Master Docket and File.** The Clerk will maintain a master docket and case file under the style "In re Silicone Gel Breast Implants Product Litigation (MDL-926)" as master file number CV 92-P-10000-S. Orders, pleadings, motions, and other documents bearing a caption similar to that of this order will, when docketed and filed in the master case, be deemed as docketed and filed in each individual case to the extent applicable and will not ordinarily be separately docketed or physically filed in such individual cases.

However, the caption may also contain a notation indicating whether the document relates to all cases or only to specified cases.

(b) **Separate Filing.** A document that relates only to a specific case and would not be of interest except to the parties directly affected by it – such as an amended complaint adding a party or a motion to dismiss a party – should bear the caption and case number of that case rather than of the master case file. Such a document will be docketed and filed in that case and not in the master case file. Please note that cases removed or transferred to this court are assigned a new case number in this court.

(c) **Address; Number of Copies.** When filing documents with the court, send only one signed original to the Clerk, U.S. District Court, Federal Courthouse, Birmingham, AL 35203. Documents should be stapled once and should not have "blue backs" or other cover sheets. Unless specifically requested by the court, do not submit additional copies to the Clerk or send informational copies to the judge's chambers.

(1) **Telephone Numbers.** The telephone number for the Docket Clerk handling these cases is (205)731-2038. Access to PACER (a computerized service for obtaining docket information) is (205)731-3502. The general telephone number for the Clerk's office is (205)731-1701.

(2) **FAX.** Litigants may transmit documents to the Clerk by FAX only if advance approval is given by the undersigned. This approval should be requested only in exigent circumstances where transmission by

other methods is not feasible. The Clerk's FAX number is (205)731-0742.

(d) **Briefs; Correspondence.** Send to the judge's chambers (Room 882, Federal Courthouse, Birmingham, Alabama, 35203) any briefs, correspondence, and other similar materials that are not due to be docketed. Send only one copy. Do not send a copy of such materials to the Clerk.

(1) **Telephone Number.** The telephone number for the judge's chambers is (205)731-1709.

(2) **FAX.** Litigants may transmit documents to the judge's chambers by FAX only if advance approval is given by the undersigned. This approval should be requested only in exigent circumstances where transmission by other methods is not feasible. The chamber's FAX number is (205)731-2243.

(e) **Discovery Documents.** Pursuant to Rule 5(d), discovery requests and responses are not to be filed with the Clerk or sent to the judge's chambers except when specifically so ordered by the court or to the extent needed in connection with a motion.

(f) **Computer Files.** Counsel using computers to prepare documents sent to the Clerk or to the judge's chambers are asked to retain computer-readable text files of these documents. The court contemplates that procedures will be established for maintaining an electronic library of these files for quick and inexpensive access by other litigants and interested parties.

4. **Service of Original Complaints; Amendment Adding Parties.**

(a) **Acceptable Service.** Exhibit B is a list of the "National Defendants" – that is, those entities that have frequently been named as defendants in these cases filed throughout the United States – showing also their national counsel and (according to their counsel) the state(s) in which they are incorporated, in which they have their principal place of doing business, and in which they will or may contest personal jurisdiction. To eliminate disputes over service of process and reduce the expense of such service, these defendants have agreed to accept service of process in these cases (without, however, waiving any objections to personal jurisdiction or venue) if a copy of the summons and complaint is sent by certified mail, return receipt requested, to the person or address shown in the Fifth Column of Exhibit B. This agreement applies to any case involving silicone gel product liability claims filed in any federal district court or in any state court of general jurisdiction.

(b) **Extension of Time to Serve.** Notwithstanding the provisions of Rule 4(j), plaintiffs shall have thirty days after the date of this order (or, if later, thirty days after the date a case is subsequently filed in, removed to, or transferred to this court) in which to effect service on defendants.

(c) **Leave to Add Parties.** Until otherwise directed, plaintiffs are granted leave, without need for any special motion or order, to add other plaintiffs to any pending (or subsequently

filed, removed, or transferred) case if all plaintiffs in the case (1) will be represented by the same counsel (or if counsel for existing plaintiffs consent to the intervention), (2) all plaintiffs are suing the same defendants, and (3) all plaintiffs had their implant(s) performed in the same state. The purpose of this authorization is to avoid unnecessary filing fees and the delays inherent in 28 U.S.C. § 1407 transfers. The joinder of such parties will not be viewed as affecting subsequent motions by either plaintiffs or defendants for separate trials under Rule 42(b). Plaintiffs choosing to add parties under this authorization are, to the extent claims are made against any of the "National Defendants" listed in Exhibit B, requested to send a copy of the amended complaint to such agent or address in addition to serving liaison counsel as specified in paragraph 5(a).

5. **Service of Other Documents.**

(a) **National Liaison Counsel.** Service of all orders, pleadings (other than the original summons and complaint), motions, briefs, and other documents will be effective on all parties when made on the following persons who, as provided in Order No. 2, have been designated as National Liaison Counsel:

(1) National Liaison Co-Counsel for Plaintiffs:

Mr. Francis H. Hare, Jr.
Hare, Wynn, Newell & Newton
Suite 800, Massey Building
290 North 21st Street
Birmingham, AL 35203
Telephone: (205)328-5330
FAX: (205)323-8276 or 324-2165

Mr. J. Michael Rediker
Ritchie & Rediker
312 North 23rd Street
Birmingham, AL 35203
Telephone: (205)251-1288
FAX: (205)324-7830

(2) National Liaison Counsel for Defendants:

Mr. Frank C. Woodside, III
Dinsmore & Shohl
1900 Chemed Center
255 East Fifth Street
Cincinnati, OH 45202
Telephone: (513)977-8266
FAX: (513)977-8141

Documents received by liaison counsel by 11:59 p.m. on Thursday of any week are considered served as of 4:00 p.m. on Friday of that week. Liaison counsel are responsible for promptly distributing copies to the parties for whom they are acting as liaison counsel on a "need to know" basis and for providing a convenient, inexpensive means by which any other parties for whom they are acting can obtain copies if desired.

(b) Additional Service.

(1) **Defaults; Sanctions.** Motions claiming default or seeking other penalties or sanctions against a party for failure to take some action within a time period measured from the date of service of a document must also be served on counsel of

record for that party (or, if the party is listed in Exhibit B, on the national counsel for that party).

(2) **Informational Copies.** If a document affects only a particular party or a particular case – for example, a motion seeking to dismiss a party in a case or to remand a case to state court – service of an additional copy upon counsel of record for that party or in that case (or, for those defendants listed on Exhibit B, their national counsel for this litigation) is encouraged, but not required.

(c) **Computer Files.** Counsel using computers to generate documents served on other parties are asked to retain computer-readable text files of these documents. It is contemplated that procedures will be established for maintaining a library of such materials for quick and inexpensive access by other litigants and interested parties.

6. **Master Pleadings; Motions; Orders.**

(a) **Master/Sample Complaints.** Plaintiffs' National Steering Committee has filed in CV 92-P-10000-S (1) a master complaint containing allegations that would be suitable for adoption by reference in individual cases and (2) a sample complaint illustrating how allegations from the master complaint can be incorporated into an individual case.

The allegations of the master complaint are not deemed automatically included in any particular case. However, in order to avoid possible problems with statutes of limitations or doctrines of repose, it shall be

deemed (except to the extent a plaintiff thereafter files an amended complaint disavowing such claims and theories or limits its claims and theories to those contained in an amended complaint) that as of this date, for cases now pending in this court (or as of the date other cases are filed in, removed to, or transferred to this court) a motion is filed in each such case to amend the complaint to add any potentially applicable claims and theories from the master complaint not contained in the complaint actually filed in that case.

(b) **Master Answers.** By October 15, 1992, each entity listed in Exhibit B will file in CV 92-P-10000-S a master answer that incorporates its defenses in law or fact to claims made against it in the various actions that are presently pending in this litigation, including any cross-claims it makes against other defendants. The answer will not attempt to provide a cross-reference to particular paragraphs or counts of the various complaints. The answer will, however, in a "generic" manner admit or deny (including denials based on lack of information and belief) the allegations typically included in claims or cross-claims made against it as well as make such additional allegations as are appropriate to its defenses or cross-claims. This may be done through allegations such as "It alleges . . . that it is incorporated in State A; that it has its principal place of business in State B; that during the period from (date) to (date) it manufactured, sold, and distributed products intended to be used in breast implant procedures; that these products were intended to be used only by trained, knowledgeable physicians and were

accompanied by warnings and instructions that adequately explained such risks as were inherent and unavoidable in the products; that these products were not unreasonably dangerous, were suitable for the purposes for which they were intended, and were distributed with adequate and sufficient warnings; that it is without knowledge or information at this time sufficient to form a belief as to any averment that one of its products was used in the implant procedure on which the plaintiff's complaint is based; that to the extent the plaintiff makes a claim for X (or under Statute Y) it is not liable because . . . ; etc."

(1) When so filed in CV 92-P-10000-S, these answers constitute an answer in each constituent case now pending or when hereafter filed in, removed to, or transferred to this court except to the extent the defendant later files a separate answer in an individual case.

(2) A defendant not listed in Exhibit B *may* also file a master answer in CV 92-P-10000-S by October 15, 1992, or within 45 days after the first case in which it is named as a defendant is filed in, removed to, or transferred to this court.

(c) **Refinement of Pleadings.** It is anticipated that an amended, more specific complaint and answer may be required before a case is scheduled for trial or remanded to a transferor court, but that amendments of pleadings prior to that time should generally be avoided.

(d) **Motions; Orders.** A motion, brief, or response that has potential effect on multiple parties (e.g., documents submitted in connection

with a motion for partial summary judgment asserting that punitive damages are not recoverable with respect to implants performed in State A) will be deemed made in all similar cases on behalf of, and against, all parties similarly situated except to the extent such other parties timely disavow such a position. Additional motions, briefs, or responses addressed to such issues should not be filed or submitted by other parties except to the extent needed because of inadequacy of the original papers, to present unique facts, or a difference in positions. Order resolving such motions will likewise be deemed as made with respect to all parties similarly situated unless the order indicates otherwise.

(e) **Motions under Rule 11 and Rule 56.** No motion shall be filed under Rule 11 or Rule 56 without leave of court.

(f) **Effort to Resolve Without Court Intervention.** Any motion relating to discovery or any other subject on which accord of affected parties might reasonably be expected shall contain a certificate that the movant has conferred with other affected parties and made a good faith effort to resolve the dispute without need for court intervention.

7. **Discovery.**

(a) **Concepts and Objectives.** The plan for document production, interrogatories, requests for admission, and depositions has been developed based on the following principles: (1) discovery should be conducted on the assumption that there may be a separate trial of each case (federal or state); (2) additional "true discovery"

will not be needed with respect to many potential witnesses who have previously testified in depositions or in trials; (3) videotaped depositions (which are also stenographically recorded) should be taken for potential use as trial testimony of all persons whose testimony will likely be needed in a number of trials, thereby enabling trials to be conducted in different courts at the same time without complications arising from unavailability of witnesses; (4) through use of a joint plaintiff-defendant federal-state library, all parties in any federal or state court should have quick and inexpensive access to, and the ability to retrieve, (A) all existing and future depositions, interrogatories, requests for admission, and trial transcripts in text-readable and searchable computer files and (B) all potentially relevant documents from the defendants and other sources that are likely to be used during depositions or at trial in more than a single case; (5) claims of confidentiality and use of "protective" orders restricting use of materials should be kept to an absolute minimum; (6) some discovery will be "national" in scope (i.e., potentially needed in various cases throughout the country), while other discovery will be "regional" (e.g., depositions from plastic surgeons performing numerous implants) and still other discovery will be "case-specific" (e.g., depositions of plaintiffs and their treating or examining physicians); (7) the plan should be designed to accommodate coordinated, cost-efficient discovery in both federal and state courts; and (8), in order to minimize unnecessary burdens and expense of redundant discovery, parties should not submit document requests, interrogatories, requests for admission,

and notices of depositions without first determining that the materials are not available in the library or are inadequate.

(b) **Plaintiffs' Steering Committee.** The court has appointed a Plaintiffs' National Steering Committee to coordinate discovery and other pretrial proceedings on behalf of the various plaintiffs. The list of these attorneys is attached as Exhibit C. The court reserves the right to change these appointments from time to time as appropriate.

(1) It is recognized that there are, and likely will continue to be, disagreements among plaintiffs with respect to various pretrial matters, particularly with respect to the planning for trial and as to whether class actions or consolidated trials may be appropriate. The designation of the Steering Committee is not intended to preclude the presentation to the court of divergent views from within the Steering Committee or by attorneys for plaintiffs who disagree with positions taken unanimously by the Steering Committee. However, counsel for individual plaintiffs should not repeat arguments, presentations, or actions of the Steering Committee.

(2) The Steering Committee may organize itself into sub-committees and may designate additional counsel to assist in performing its responsibilities.

(3) At least in states in which a substantial number of implant cases have been or may be instituted (whether in federal or state court), there will also be a state (or local) liaison counsel or steering committee,

with responsibilities for similar coordination in management of discovery that is primarily state-wide or local, such as discovery from surgeons or hospitals which have been involved in many implant and explant/removal procedures. It is expected that, if a person or committee is established by the state courts to coordinate implant litigation within that state, the same attorneys should ordinarily be designated to perform similar functions for the federal cases filed in that state.

(c) **Joint Depository.** A joint plaintiffs-defendants federal-state document depository and library will be maintained in the United States Courthouse at 100 East Fifth Street, Cincinnati, Ohio, 45202 (telephone: 513-684-6688; FAX: 513-684-5853) and supervised by Tina J. Crowe. The depository will store all materials produced by parties and third-parties that may be needed in more than single case, including documents, interrogatories, requests for admission, requests for production of documents, depositions, trial transcripts, and similar materials. These materials will be made available to litigants in any federal or state case involving implant product liability claims. It is anticipated that materials in the depository should be available from the depository for such distribution by December 1, 1992.

(1) The expenses of the depository, including the costs of imaging of documents and the compensation paid to Ms. Crowe to the extent not payable as an employee of the federal judiciary, shall be initially divided equally between the Plaintiff's National

Steering Committee and the national defendants listed in Exhibit B.

(2) Reimbursement of these expenses may be obtained by imposing user fees, but these fees will be kept to the minimum necessary to fund the costs of the depository incurred by reason of this litigation. The depository will not be conducted as a "profit-center."

(3) Plaintiffs' Steering Committee has indicated that it expects to establish additional regional electronic depositories.

(d) **Numbering.** All materials will be uniquely identified by a prefix of as many as three letters and a page number of as many as nine digits. This combination of letters and digits should then be used throughout the discovery process and at trials whenever referring to a particular document or page. All reasonable efforts should be made to avoid having the same page being assigned more than one such identifying number except when there is a need to account for different copies of the same document or page, for example because of special notations being placed on a document.

(e) Documents.

(1) Documents produced by the plaintiffs, defendants, and third-parties pursuant to Rules 33, 34, and 45 will be submitted to the depository, as will a copy of interrogatories (and responses), requests for admission (and responses), depositions, trial transcripts, and other similar materials.

(2) The "manufacturer" defendants have been directed to submit to the depository by September 15, 1992, the documents previously requested from them; and the "supplier" defendants ('21' International Holdings, General Electric, and Union Carbide) have been directed to submit to the depository by October 15, 1992, the documents requested from them.

(A) Some additional time may be needed by some defendants to produce some of the requested documents. These are to be submitted as soon as possible after the due dates.

(B) The documents to be produced include all non-privileged materials that are potentially relevant in any of the cases or that are reasonably calculated to lead to relevant evidence. After the production has been accomplished, the Plaintiffs' National Steering Committee and the particular defendant will prepare a joint statement describing the nature and scope of the documents produced that can serve as the functional equivalent of a Rule 34 request and response, enabling other litigants to understand what has been produced.

(C) Each defendant shall file by November 1, 1992, a list of any otherwise relevant documents that are not produced based on a privilege or a protection (such as for work-product materials). Documents may be withheld only

if privileged or protected against disclosure in each court (federal or state) in which they have been sued.

(D) The objective that defendants producing documents under this plan be relieved of redundant requests from plaintiffs in other federal and state cases can be accomplished only if plaintiffs can be reasonably confident that all potentially relevant documents are either produced or are specifically identified as withheld pursuant to a legitimate claim of privilege or protection against disclosure. A defendant's failure to either produce or identify as withheld a relevant document will be viewed by the court as a serious infraction of its orders, justifying appropriate sanctions unless exceptional circumstances justify its failure. Upon learning that there are any additional relevant documents in its possession or under its control which have not been produced or identified, a defendant is under an obligation to promptly make known the existence of the documents (including the reason for its failure) and submit the documents to the depository or, if withheld under a claim of privilege or protection, identify the documents.

(3) Pleadings, interrogatories, trial transcripts, and similar materials will, to the extent feasible, be stored in computerized text-readable and searchable format. Depositions will be stored both in the form of text-readable and searchable computer files

and on video-tape. Other documents such as letters, reports, photographs, etc. (including those appended to a deposition) will be "imaged" under a contract with DocuQuest approved by the court in Order No. 4 and then made available to litigants on CD-ROM disks or other suitable media unless, because of the nature of the materials, they are unlikely to be used in other than a single case (e.g., medical history records of a particular plaintiff).

(4) A summary will be prepared by Plaintiffs' National Steering Committee and reviewed by the defendants, which identifies by number and describes (in neutral words that would be suitable for use by a court in preparing a list of exhibits) the various documents. This summary will be prepared in a computerized data-base format and made available to all parties, who then may add private, work-product comments as separate fields in their own copy of the data-base.

(5) All "protective" orders previously entered in any of the cases part of MDL-926 under Rule 26(c) are (with the exception of those designed to keep confidential the identity and medical condition or history of plaintiffs or putative class members) hereby vacated and voided effective November 15, 1992. Any party seeking to impose restrictions on access to or use of any materials under Rule 26(c) shall file by November 1, 1992, a motion identifying with particularity the materials for which the protection is

sought and the proposed terms and conditions of any such protection. If materials are subject to a protective order entered by another court in a case that is not part of MDL-926, the affected parties are expected to waive, to the extent feasible, any rights under such orders to keep such materials confidential and, if necessary, to seek relief from the court in which the protective order was entered. To the extent any materials remain or become subject to a protective order, that fact will be indicated in a separate field on the summary described in paragraph (4) above.

(6) Tina J. Crowe, Supervisor of the Depository, will prepare and make available before December 1, 1992, an informational booklet explaining how materials can be obtained from the depository.

(7) Each party shall preserve all documents and other records and exhibits potentially relevant to the subject matter of this litigation. Subject to further order of the court, parties may continue routine erasures of computerized data pursuant to existing program, but they shall (A) notify opposing counsel about such programs and (B) preserve any printouts of such data. Requests for relief from this directive will receive prompt attention from the court. The parties are to confer and attempt to agree on arrangements for the preservation or disposition of explanted/removed materials.

(f) Depositions.

(1) **Schedule.**

(A) **National Defendants.** Depositions of current and former employees of the "National" defendants may commence after October 15, 1992, and are to be completed by March 31, 1993. These should be taken on the assumption they may be used as trial testimony. They should be recorded both on video-tape and stenographically, with a computer disk in text-readable form also being obtained. The direct examination should be made by the party who would most likely be presenting the testimony of that person at trial. If a potential deponent has not previously testified in a deposition or at trial, it may be appropriate to arrange for a "discovery" deposition by opposing parties prior to the "trial-type" deposition.

(B) **Plaintiffs.** Depositions of plaintiffs may commence after December 1, 1992. For most of these, the principal purpose will be for "discovery" purposes and will likely be noticed by defendants after the plaintiff has answered interrogatories providing "core information" about the plaintiff's condition and claims of damage. The parties are given leave to conduct these depositions by video-tape recording (provided a stenographic record is also made), but there is no requirement for video-taping. No cut-off date can be established at this point in view of the potential for additional cases and the lack of certainty as to trial dates.

(C) **National Experts.** Depositions of "national" experts – those whose testimony may be used in different trials around the country – may commence after March 31, 1993, and should be completed by May 31, 1993. These should be taken on the assumption they may be used as trial testimony. They should be recorded both on video-tape and stenographically, with a computer disk in text-readable form also being obtained. The direct examination should be made by the party who would most likely be presenting the testimony of that person at trial. If a potential deponent has not previously testified in a deposition or at trial, it may be appropriate to arrange for a "discovery" deposition by opposing parties prior to the "trial-type" deposition. It is recognized that supplemental depositions may be needed from time to time, for example if there is a change in the state-of-knowledge regarding implants and their consequences.

(D) **Plastic Surgeons; Hospitals.** Depositions of surgeons and hospital personnel involved in implant or explant/removal procedures, some of whom may be named as defendants in some cases, may commence after May 31, 1993. These depositions are likely to have two phases or aspects – first, general information that is not plaintiff-specific (e.g., education, what they knew or were told about implant materials and when, what they usually

advised patients, etc.) and second, particular information that is plaintiff-specific. It is anticipated that this general information would be obtained in a trial-type video-taped deposition for potential use in all appropriate cases and that this could be accomplished during Summer 1993. Some plaintiff-specific depositions might be conducted as early as Summer 1993, but the time required for all of these will depend upon the number of procedures performed by the deponent and the potential trial dates for a particular plaintiff.

(E) **Treating Physicians.** Depositions of physicians who have treated plaintiffs may commence in some cases as early as June 1993. The time required to complete these will be set as potential trial dates are determined for particular cases.

(F) **Defendant's Examining or Consulting Physicians.** Depositions of physicians who examine plaintiffs under Rule 35 on the request of a defendant or who may otherwise be called by a defendant to express opinions regrading a plaintiff's condition should ordinarily be taken after the depositions of the plaintiff's treating physicians. In some cases this might occur as early as August 1993. The time required to complete these will be set as potential trial dates are determined for particular cases.

(G) **Other Witnesses.** Depositions of other persons (e.g., members of plaintiff's family) will be scheduled based on the potential dates of particular cases. It is not expected that any of these would commence before June 1993. If a deposition is needed to provide the evidentiary foundation for admissibility of documents (e.g., under Evidence Rule 803(6) as evidence of the truth of assertions contained in a business record), it is expected that, to save costs, this would be accomplished either by a telephone deposition or by a deposition under Rule 31.

(2) **Method of Examination.** When taking depositions for potential use in a number of cases: (A) start with full examination (direct, cross, and redirect) on the matters of general interest before proceeding into any additional interrogation that is plaintiff-specific; (B) avoid identifying items such as "I'm Mary Smith and I'm representing Jane Doe" that could be confusing when the deposition is used in other cases; and (C) do not repeat examination merely to make it specific to a particular case. For example, if Dr. Don Jones testifies that he didn't tell *any* of his patients that there was a risk that X might happen, don't ask him for the same information about each individual plaintiff.

(3) **Objections.** Even in depositions taken primarily for use at trial, it is rarely necessary to state objections to questions during the deposition. Most objections can –

and should – be made for the first time at trial when a deposition is offered. Any objections that are made during the deposition must be stated concisely and in a non-argumentative and non-suggestive manner, such as would be appropriate if the examination was conducted before a judicial officer. A party may instruct a deponent not to answer a question only when necessary to preserve a privilege, to enforce a limitation on evidence imposed by the court, or to present a motion under Rule 30(d).

(4) **Number of Examiners.** Counsel should exercise self-restraint by not attending depositions that can be fairly conducted by others having a similar interest. One or two attorneys are to be designated by each side to conduct the principal examination of the deponent. While other counsel may ask additional questions, these should be limited to matters not already covered, and it is preferable that these additional questions be asked by the same counsel who have conducted the prior examination. It will be permissible to take periodic recesses during a deposition in order for examining counsel to consult with their colleagues about additional lines of examination, but such recesses should not be used to "coach" the deponent.

(5) **Disputes during Depositions.** Counsel should attempt to resolve disputes arising during depositions without need for court intervention. Disputes that cannot be so resolved may, if they might result in the need to conduct a supplemental deposition,

be raised with this court by telephone, either to the undersigned (205-731-1709) or to Magistrate Judge Elizabeth Campbell (205-731-0364). It is expected that disputes between the parties should be addressed to this court rather than to the district court in which the deposition is being conducted, and that the undersigned will exercise the powers conferred by 28 U.S.C. § 1407(b) to deal with disputes involving non-party deponents.

(6) **Use at Trial.** A deposition taken pursuant to this plan (including, when filed in the document depository, depositions previously taken in these cases and depositions previously or subsequently taken in any other silicone gel implant litigation in federal or state courts) shall be considered as satisfying the requirements of Rule 32(a) for use at trial in any federal court action involving silicone gel implants (subject to meeting the conditions stated in one of the numbered paragraphs of that subdivision) against any entity that –

(A) at the time the deposition is taken is a party in any case then consolidated in this court under CV 92-P-10000-S, or

(B) after the deposition is taken becomes a party in any case consolidated in this court under CV 92-P-10000-S, unless within 45 days after first becoming a party it files with this court a written request that one or more specifically identified depositions not be used in the case(s) in which it is a

party. If such a request is filed, other parties wanting to use the deposition(s) in the case may thereafter notice the deponent for a supplemental deposition, including one by telephone or on written questions under Rule 31. In such depositions the deponent should first be asked whether he or she reaffirms the testimony previously given. If the answer is "yes," further examination of the deponent should be limited to issues and items not covered in the original deposition.

The parties to this litigation are hereby ENJOINED from raising, with respect to any deposition usable against them in federal court actions, any objection in any state court action involving silicone gel implants to the use of the deposition based upon the fact that the deposition was not taken in the state court action. Any request for relief from this injunction must be filed with this court within 30 days from the date the deposition is filed in the depository or from the date it first becomes a party in this litigation.

These provisions do not preclude objections to use of a deposition premised upon the availability of the deponent to be called in person, nor do they preclude objections to the admissibility of particular items of testimony in a deposition on evidentiary grounds such as relevance, hearsay, etc.

To facilitate usability of depositions in state court actions involving entities that are not and may never be parties in the federal

cases, the parties are encouraged, if no other procedures have been established by the state courts, to issue "cross notices" of depositions to the additional state-court parties.

(g) Interrogatories.

(1) **To Plaintiffs.** The National Defendants will, after conferring with Plaintiffs' National Steering Committee, file by October 15, 1992, a single master set of interrogatories and document requests designed to elicit (to the extent not previously obtained) from each named plaintiff (but not from putative class members) "core" information needed to conduct an efficient deposition of the plaintiff. While plaintiffs may be asked to identify potential "fact" witnesses relating to liability or damage claims, they are not to be asked so-called contention interrogatories. Plaintiffs are to serve answers and make documents available by November 15, 1992 (or within 30 days after the case is filed in, removed to, or transferred to this court as a part of CV 92-P-10000-S), but the parties are granted leave to agree (and are expected to agree) on appropriate extensions of time, taking into account the number of plaintiffs that a particular law firm may be representing and the time when counsel would realistically be ready to proceed with a deposition of a particular plaintiff.

(2) **To Defendants.** Plaintiffs' National Steering Committee will, after conferring with counsel for each of the National Defendants, serve by March 31, 1993, a set of

interrogatories directed to that defendant. These interrogatories should be limited to questions eliciting information (e.g., its relationship to other defendants and trade organizations to which the defendant belongs) that might reasonably be expected to be used as evidence at a trial. So-called contention interrogatories will not be allowed. Given the limited purpose of these interrogatories, defendants should be able to serve their answers within 30 days after being served with the interrogatories.

(h) **Additional Discovery Requests.** The parties will confer concerning, and attempt in good faith to agree upon, any additional discovery requests not described above. The court expects that any such requests should not seek information already obtained and available from the depository absent good cause to believe that the available information is inadequate or incorrect.

(i) **Deadlines Imposed by Other Courts.** Orders issued by other courts imposing dates for initiation or completion of discovery are, when a case is removed or transferred to this court, vacated and replaced by the schedule provided in this order.

(j) **Exceptional Cases.** Any party may move for relief from the prescribed discovery schedule when merited by special circumstances, such when a plaintiff is "in extremis" or to obtain information pertinent to critical preliminary issues (e.g., forum nons convenience issues respecting claims by foreign plaintiffs).

(k) **Special Master.** Pursuant to Rule 53(a), the court hereby appoints Francis E. McGovern

as Special Master for the purpose of assisting this court in the fair and efficient coordination of discovery conducted in federal court with that conducted in the various state courts in which similar cases are or may hereafter be filed.

8. **Class Actions.** In Order No. 3 this court extended indefinitely the time within which putative class members can elect to exclude themselves from the class action that was previously certified by the United States District Court for the Southern District of Ohio in Donna Dante et al. v. Dow Corning Corp. et al, (No. 1:92-057), which is now pending in this court as Case No. CV 92-P-10060-S. This court has not determined whether the class certification in Dante will be retained, vacated, or modified, or whether a class should be certified in any of the other cases in which such a request has been or may hereafter be made. Such decisions will be made at a future date, with appropriate notification being given to persons to be affected thereby. Under current law, statutes of limitations are probably considered as tolled for members of the Dante class during the pendency of the class certification.

9. **Trial(s).** This court has not yet made any determination whether any cases should be consolidated for trial, whether some issues should be tried separately from others, whether any cases should be transferred to this court under 28 U.S.C. § 1404 or 1406, etc. For planning purposes, however, it is anticipated that some cases might be ready for trial on liability and damages as early as – but, absent extenuating circumstances, not earlier than – Fall 1993. There is the possibility that some special

issues, such as the responsibility of one defendant for the actions of another, might be ready for separate trial prior to that time.

This the 15th day of September, 1992.

/s/ Sam C. Pointer, Jr.
United States District Judge

Attachments:

A – Abbreviated Order for Filing in Individual Cases
B – Information Concerning National Defendants
C – Plaintiffs' National Steering Committee

EXHIBIT C

Plaintiffs' National Steering Committee

Co-Chairmen:

Mr. Stanley M. Chesley
Waite, Schneider, Bayless & Chesley
1513 Central Trust Tower
Fourth & Vine Street
Cincinnati, OH 45202
Telephone: 513-621-0267
Fax: 513-621-0262

Mr. Ralph I. Knowles, Jr.
Doffermyre, Shields, Canfield & Knowles
1600 The Peachtree
1355 Peachtree Street
Atlanta, GA 30309
Telephone: 404-881-8900
Fax: 404-881-3007

Members:

Ms. Margaret M. Branch
The Branch Law Firm
2025 Rio Grande Boulevard NW
Albuquerque, NM 87104
Telephone: 505-243-3501
Fax: 505-243-3534

Mr. Dan C. Bolton
Wilson, Szumowski & Bolton
655 Montgomery Street, 16th Floor
San Francisco, CA 94111-2632
Telephone: 415-421-2800
Fax: 415-421-2881

Ms. Elizabeth Joan Cabraser
Embaracadero Center West
275 Battery Street
30th Floor
San Francisco, CA 94111
Telephone: 415-956-1000
Fax: 415-956-1008

Mr. Lawrence S. Charfoos
Charfoos & Christensen
4000 Penobscot Building
Detroit, MI 48226
Telephone: 313-963-8080
Fax: 313-963-0243

Mr. Harry L. Durant
Houssiere & Durant
Three Post Oak Central
Suite 810
1990 Post Oak Boulevard
Houston, Texas 77056
Telephone: 713-626-3700
Fax: 713-626-3709

Mr. Wendell Gauthier
3500 N. Hullen Street
Metairie, LA 70002
Telephone: 504-456-8662
Fax: 504-856-8624

Mr. Robert Gordon
Weitz & Luxenberg
40 Fulton Street
New York, NY 10038
Telephone: 212-720-7200
Fax: 212-227-7640

Mr. LeRoy Hersh
Hersh & Hersh
2080 Opera Plaza
601 Van Ness Avenue
San Francisco, CA 94102-6388
Telephone: 415-441-5544
Fax: 415-441-7586

Plaintiffs' National Steering Committee (cont'd)

Mr. Mark Hutton
Michaud, Hutton & Bradshaw
8100 East 22nd Street North
Suite 1200
Wichita, Kansas 67226
Telephone: 316-686-3404
Fax: 316-686-1077

Mr. Arnold Levin
Levin, Fishbein, Sedran & Berman
320 Walnut Street Suite 600
Philadelphia, PA 19106
Telephone: 215-592-1500
Fax: 215-592-4663

Mr. Aaron Levine
1320 19th Street NW
Suite 500
Washington, D.C. 20036
Telephone: 202-833-8040
Fax: 202-833-8046

Mr. Salvador Liccardo
Suite 200
1960 The Alameda
San Jose, CA 95126
Telephone: 408-244-4570
Fax: 408-244-3294

Ms. Dianne M. Nast
Kohn, Nast & Graf, P.C.
1101 Market Street
Suite 2400
Philadelphia, PA 19107
Telephone: 215-238-1700
Fax: 215-238-1968

Mr. Howard A. Specter
Specter Law Offices, P.C.
Koppers Building
26th Floor
Pittsburgh, PA 15219
Telephone: 412-642-2300
Fax: 412-642-2309

Ms. Gayle Troutwine
Williams & Troutwine, P.C.
1001 SW 5th
Suite 1900
Portland, OR 97204
Telephone: 503-295-2924
Fax: 503-295-3720

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)	)	Master File No. CV 92-P-10000-S
HEIDI LINDSEY, et al., Plaintiffs, -vs.- DOW CORNING CORP., et al., Defendants.	)	Civil Action No. CV 94-P-11558-S

ORDER NO. 15

(Granting Preliminary Approval to Settlement Agreement, Conditionally Certifying Settlement Class, Approving Notice, and Scheduling Fairness Hearing)

(Filed Apr. 1, 1994)

After reviewing the Breast Implant Litigation Settlement Agreement ("Settlement Agreement") submitted by the parties in *Lindsey, et al., v. Dow Corning Corp., et al.*, Civil Action No. CV 94-P-11558-S (the "Lindsey action"), and being satisfied that, with the modifications effected by this order, the proposed settlement appears to meet the applicable criteria for preliminary approval, the Court preliminarily approves the proposed class action settlement described in the Settlement Agreement and provisionally orders, subject to further alteration or amendment under Fed. R. Civ. P. 23(c), as follows:

1. The Lindsay action is certified as a class action for settlement purposes under Fed. R. Civ. P. 23(a), 23(b)(3), and 23(c).

(a) The Lindsay action will be maintained on behalf of a non-mandatory ("opt-out") Plaintiff Settlement Class (the "Class") that, except as provided in paragraph 1(b), consists of –

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more included Breast Implants (or with any Breast implants made with any Included Breast Implant materials), whether or not such Breast Implants have been or may later be removed, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural Mother is a person described in paragraph 1(a)(1) and who was born after the date his or her Mother had a breast implant, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her Mother's having had a breast implant; and

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in paragraph 1(a)(1) or 1(a)(2).

(b) Excluded from the Class are the following:

(1) breast implant recipients all of whose breast implants are identified as having been manufactured or distributed by McGhan Medical Corp., INAMED Corporation, Minnesota Mining and Manufacturing Co. ("3M"), Porex Medical Technologies Corp. (or related companies), or by Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B to this Order;

(2) breast implant recipients who are not citizens of the United States if (A) all of their breast implantations were performed outside the United States and (B) they have received any compensation for breast implant injuries or expenses under the laws or procedures of another country;

(3) breast implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not

represented by counsel in such settlement and the settlement involved a payment of less than $15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by fraud by a Settling Defendant;

(4) breast implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant for a breast implant claim or shall have had a final judgment after a trial on the merits entered against them on a breast implant claim in favor of a Settling Defendant;

(5) breast implant recipients who elect to exclude themselves from the Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994; and

(6) any person or entity described in paragraph 1(a)(2) or 1(a)(3) whose status as a class member depends on class membership of a recipient excluded under paragraph 1(b)(1) through 1(b)(5).

(c) For purposes of this Order, the terms –

(1) "Breast Implant" means any mammary prosthesis containing or consisting of silicone, silicone gel, or saline; it does not include a silicone injection. The terms "Included Breast Implants" means Breast Implants manufactured, distributed, designed, fabricated, sold, produced, or otherwise placed in the stream of commerce by any Settling Defendant or Released Party.

(2) "Breast Implant Materials" means materials, products, or components used in the manufacture of a Breast Implant. The term "Included Breast Implant Materials" means Breast Implant Materials manufactured, distributed, designed, fabricated, sold, produced, or otherwise placed in the stream of commerce by any Settling Defendant or Released Party.

(3) "Breast Implant Recipient" means a person in whose body one or more Breast Implants were implanted before June 1, 1993, whether or not already or later removed,

(4) "Settling Defendants" means the companies listed in Exhibit A to this Order, with such additions or corrections as may be approved by the court.

(5) "Released Parties" means the Settling Defendants; the individuals and entities listed in Exhibit B to this Order (with such additions or corrections as may be a approved by the court); their respective present and former foreign and domestic parents, subsidiaries, and affiliates; their respective foreign and domestic predecessors, successors, sales representatives, independent sales representatives, distributors, transferees, insurers, and assigns; and their respective present, former, and subsequent officers, directors, agents, servants, proprietors, owners, shareholders, and employees, except that the term "Released parties" –

(A) does not include doctors, hospitals, and other health-care providers who furnished medical services directly to a Class Member unless they are specifically named in Exhibit B, and

(B) does not include doctors specifically named in Exhibit B with respect to claims against them based upon their furnishing medical services directly to a Class Member.

(6) "Bioplasty Defendants" means Bioplasty, Inc.; Bio-Manufacturing, Inc.; Utoplasty, Inc.; and New Uroplasty, Inc.

"Mentor Defendants" means Mentor Corporation; Mentor Polymer Technologies, Inc.; Mentor OOO, Inc.; Mentor H/S, Inc.; Mentor Urology, Inc.; Mentor International, Inc.; and Tecknar Corp.; and their respective predecessors, successors, parent and subsidiary companies and divisions, and current and former attorneys, officers, directors, agents, distributors, sales agents, and employees.

(d) The class claims that are certified to be maintained on behalf of Class Members are limited to those against any of the Settling Defendants and the Released Parties and related to or involving breast implants.

(1) Claims against the Bioplasty or Mentor Defendants, although not certified as class claims in the Lindsey action, are generally precluded as a result of bankruptcy proceedings involving the Bioplasty Defendants in United States

Bankruptcy Court in Minnesota, BK 4-93-2600, BK 4-93-2603, and BK 4-93-2604, and as a result of the mandatory settlement with the Mentor Defendants approved in Order No. 14 in CV 93-P-11433 and in Master File No. CV 92-P-10000-S.

(2) Claims against any other manufacturer, distributor, or supplier of Breast Implants or Breast Implant Materials, or against physicians, hospitals, or other healthcare providers who are not Released Parties are not certified as class claims by this Order and are not released or dismissed under the Settlement Agreement.

(e) Subject to further orders of the Court –

(1) Plaintiffs Heidi Lindsey, Cynthia Bullock, Margaret Abner, Dorothy Dressler, Rita Thompson, Donna Dante, and Joy Bryan are designated as Representative Plaintiffs for the Class.

(2) The following attorneys are appointed as Settlement Class Counsel and as the initial members of the Settlement Committee: Margaret Moses Branch; Elizabeth J. Cabraser; Stanley M. Chesley; Michael T. Gallagher; and Ralph I. Knowles, Jr.

The Court reserves the power to appoint additional and substitute Representative Plaintiffs, Settlement Class counsel, and Settlement Committee Members and to define appropriate subclasses, including the designation of

representatives and appointment of counsel for such subclasses as necessary.

(f) Confirmation and permanent certification of the Class is conditioned upon a showing, to the court's satisfaction, that the proposed settlement described in the Settlement Agreement is fair, adequate, and reasonable, is in the best interest of the class, and should be approved under Fed. R. Civ. P. 23(e). If the proposed settlement is not approved, the provisional class certification will be vacated, the Plaintiffs and Settling Defendants will retain all rights to support or oppose certification of the Lindsey action for litigation purposes, and provisional certification may not be used by plaintiffs or defendants in support of any argument for or against certification of any other class. Neither this provisional certification nor, if ultimately approved, the permanent certification of the Class to consummate the Settlement Agreement constitutes a determination by the court as to whether a plaintiff class should be certified for purposes of trial or settlement with any other person or entity involved in the manufacture, distribution, or implantation of Breast Implants or Breast Implant Materials.

(g) The effect of class allegation in the Lindsey action on class certification in *Dante, et al. v. Dow Corning Corp., et al.*, CV 92-P-10060-S, ("the Dante action") and in any other action commenced in or removed to federal court as a class action shall be as follows:

(1) Thirty days after an order confirming and permanently certifying a class in the Lindsey action has (after any

appeals) become final, (A) class certification in the Dante action shall be deemed to be vacated, (B) proposed class certification in any other federal action then pending shall be deemed as denied, and (C) all persons covered by the class definition in the Lindsey action shall be deemed as members of the Lindsey class unless they opt out in accordance with the procedures specified for the Lindsey action, without regard to whether they were members of the Dante class, had opted out of the Dante class, or were putative members of another proposed class. Provisional or final certification of a class in the Lindsey action does not affect the class action order entered with respect to the Mentor Defendants as approved in Order No. 14 in CV 93-P-11433 and in Master File No. CV 92-P-10000-S.

(2) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the class definition in the Dante action from January 24, 1992, the date of commencement of the Dante action, until the earliest of (A) the date such person opted out of the Dante action, (B) 30 days after the date such person opts out of the Lindsey action, or (C) the date an order confirming and permanently certifying a class in the Lindsey action has (after any appeals) become final.

(3) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the

class definition in the Lindsey action from March 23, 1994, the date of commencement of the Lindsey action, until 30 days after the earlier of (A) the date such person opts out of the Lindsey action or (B) the date the provisional class certification in the Lindsey action is vacated or is modified to eliminate such persons as a class member.

(4) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the proposed class definition in any other case (other than the Dante and Lindsey actions) brought in federal court from the date of commencement of such case until the earlier of (A) the date certification of such class has been denied, (B) 30 days after the date such person opts out of the Lindsey action, or (C) the date an order confirming and permanently certifying a class in the Lindsey action has (after any appeals) become final.

2. The terms of the Settlement Agreement are provisionally approved, with the following implementing orders and modifications:

(a) The amount to be paid into Designated Fund VI, which is to cover all fees and expenses of attorneys (whether court-appointed or privately-retained) and all costs of class notice and settlement administration, is established at 25% of the total settlement amounts and will be paid as payments are made by Settling Defendants throughout the period of the Settlement Agreement, approximately 15% from the amounts prescribed in the Settlement Agreement for

Designated Funds I through V and approximately 30% from the amounts prescribed in the Settlement Agreement for the Disease Compensation Program. The court will by subsequent order establish procedures for making and paying claims under Designated Fund VI, and if Designated Fund VI exceeds the fees, expenses, and costs approved by the court, the excess will be distributed to Class Members as the court may determine, after consulting with the Claims Administrator and Plaintiffs' Settlement Counsel. The funds recovered under this settlement are not subject to any additional charge or assessment under Order No. 13 in CV 92-P-10000-S, which order, however, otherwise continues in effect except that moneys already or later collected under Order No. 13, shall be added to, administered as part of, and disbursed under the procedures to be established for, Designated Fund VI.

(b) Judge Ann Tyrrell Cochran of Houston, Texas, is appointed as Claims Administrator, effective April 7, 1994, under the authority of Federal Rule of Civil Procedure 53 and in the exercise of the court's general powers and responsibilities over class action settlements. Her actions as Claims Administrator (and those of her employees or agents) in collecting, collating, processing, evaluating, and paying claims will constitute judicial actions of this court and be protected to the maximum extent allowable by law, by the doctrine of judicial immunity.

(c) In the event of direct conflict between the terms of the Notice approved by the court and the terms of the Settlement Agreement, the Notice will take precedence.

(d) The provisions of section III.E of the Settlement Agreement, relating to Foreign Claimants, will be modified as follows:

(1) A "Foreign Claimant" means a breast implant recipient who is otherwise a member of the Lindsey Class if (A) such person is not a citizen of the United States and (B) all of such person's breast implants were implanted outside the United States.

(2) A foreign Claimant may opt out of the Lindsey Class by completing and returning the Exclusion Form by June 17, 1994. by so doing, the Foreign Claimant will preserve such rights, if any, that the person may have to file or pursue a claim related to breast implants against the Settling Defendants and Released Parties in the federal and state courts of the United States or in the courts or administrative tribunals of another country.

(3) A Foreign Claimant who does not opt out of the Lindsey Class by June 17, 1994, will, if such person fails to make a claim or register in the Lindsey action by December 1, 1994, not be entitled to any benefits under the Lindsey settlement, will be precluded from filing or pursuing a claim related to breast implants against the Settling Defendants and Released Parties in the federal and state courts of the United States, but will have such rights, if any, as that person may have to file or pursue such claims against the Settling Defendants and

Released Parties in the carts or administrative tribunals of other countries.

(4) A Foreign Claimant who does not opt out of the Lindsey Class by June 17, 1994, will, if such person makes a claim or registers in the Lindsey action by December 1, 1994, be entitled to participate in benefits provided to Lindsey Class Members (exclusive of benefits under Designated Funds I through V) subject to the following:

(A) The Foreign Claimant may participate in benefits under the Disease Compensation Program, but the amount of benefits to be paid to such person is subject to being adjusted downward by the court, relative to similar amounts paid to other Class Members, (i) to account for differences between compensatory awards typically recovered in federal and state courts of the United States and those obtained in the courts or tribunals of the country where the breast implants occurred and (ii) to assure that the total amounts paid to Foreign Claimants under the Disease Compensation Program do not exceed the maximum amount set aside for such persons under paragraph III.E.2 of the Settlement Agreement.

(B) A Foreign Claimant affected by a potential downward adjustment under paragraph 2(d)(4)(A) of this Order will be so notified and at that time afforded the opportunity to opt

out of the Lindsey Class, subject to repayment of any amounts already paid to such person from the settlement funds.

(C) A Foreign Claimant who opts out under paragraph 2(d)(4)(B) may pursue such rights, if any, as that person may have to file or pursue such claims respecting breast implants against the Settling Defendants and Released Parties in the courts or administrative tribunals of other countries, but will be precluded any such claim in the federal and state courts of the United States. Moneys tentatively allocated under this settlement to Foreign Claimants who so opt out will be reallocated among other Class Members, including remaining Foreign Claimants, as the court may direct.

(e) Notwithstanding language of the Settlement Agreement that at various places (e.g., guidelines for payments under Fund I, relating the Medical Diagnostic/Evaluation Fund) indicates that Settlement Class Counsel are to make determinations relating to the allocation of funds among potentially competing Class Members, such decisions will be the responsibility of the court after consultation with the Class Administrator. In view of the possibility of disputes that may place some Class Members in conflict or competition with other Class Members, the role of Settlement Class Counsel in such matters will be to provide advise to the Claims Administrator and court.

(f) Through further orders, the court will, from time to time, establish other deadlines and procedures as may be called for in the Settlement Agreement.

(g) The name, address, and other identifying information of Class Members (including those who call the Settlement Information Line and those who opt out of the settlement) will be kept confidential and private except to the extent needed for proper administration of the terms of the settlement.

3. The court approves the Notice Program attached as Exhibit C to this Order and the contents of the attached abbreviated Notice to be used in selected newspapers and magazines. The court will subsequently approve a detailed Breast Implant Litigation Settlement Notice and Forms, for mailing to Class Members. Dissemination of these notices, in conjunction with the other steps set forth in the Notice Program, constitutes the best notice practicable under the circumstances, and, when performed, should provide due and sufficient notice to all members of the class and satisfy the requirements of due process and Fed. R. Civ. P. 23. The parties shall use their best efforts to commence the Notice Program by April 11, 1994. The parties shall submit a certificate describing and certifying their compliance with the notice requirements of this Order by July 17, 1994. Any defendant desiring to publish, mail, or otherwise disseminate court-approved notices at times or in locations, publications, and media in addition to those prescribed in the Notice Program may do so, but the cost will be borne by that defendant

and not reduce the defendant's payment obligations under the settlement.

(4) The court will hold a formal fairness hearing (the "fairness hearing") to determine whether to grant final approval to the proposed Settlement Agreement, as fair, adequate, and reasonable, to confirm or modify certification of the Settlement Class, and to issue its Final Order and Judgment thereon. This hearing will be held on August 18, 1994, at 9:00 a.m., and at the United States Courthouse, 1729 Fifth Avenue North, Birmingham Alabama. The hearing may, from time to time and without further notice to the class, be moved to another facility in Birmingham or continued or adjourned by the court.

(a) To maintain orderly proceedings and to afford a reasonable opportunity to be heard to those who wish it, any Class Member wishing to appear in person, individually or through counsel, and be heard at the fairness hearing must submit a written notice of intent to appear, postmarked no later than June 17, 1994, mailed to the Post Office Box established by the parties for that purpose, as set forth in the attached Notices.

(b) Any member of the Settlement Class wishing to submit a written comment to support or oppose any aspect of the Settlement Agreement, the certification of the Settlement Class, or the Settlement approval process, may do so in writing, without the necessity of retaining counsel or making any formal appearance, provided such written comments are postmarked no later than June 17, 1994, and mailed to the Post Office

box established for that purpose as set forth in the attached Notices.

(c) Members of the Settlement Class may exclude themselves (opt out) from the Class by following the procedures set forth in the Notices, including the individual signature and return of the Exclusion Form to the Post Office Box provided it is received or postmarked no later than June 17, 1994.

(d) The Settling Parties shall submit their opening papers in support of final settlement approval by May 17, 1994, and shall submit a report on the status of the claims and reply to any settlement comments or objections after the opt-out and objection deadlines, and in advance of the fairness hearing.

5. The Settlement Agreement, with Exhibits, shall be made available for public inspection in the Clerk's office during regular business hours.

6. In aid of the court's jurisdiction over the Settlement Class provisionally certified in this Order, and to assure the fair and orderly conduct and completion of the settlement consideration process described in this Order and the approved Notices, the court hereby:

(a) temporarily stays and suspends, pending further order, any and all class certification or class notice proceedings in any and all federal and state civil actions to the extent that any classes proposed or certified in such actions purport to include persons and claims included in the complaint in the Lindsey action, in the Settlement Agreement, and in the class definition provisionally approved in this order; and

(b) temporarily enjoins the commencement of trial in any federal or state court during the period from June 16, 1994, to August 18, 1994, of any breast implant action against a Settling Defendant or Released Party by any Class Member who shall not have timely elected to be excluded from the Settlement Class.

This the 1st day of April, 1994.

/s/ Sam C. Pointer, Jr.
Sam C. Pointer, Jr.
United States District Judge

EXHIBIT A
Settling Defendants

Aesthetech Corporations
American Heyer-Schulte Corporation
f/k/a Heyer-Schulte Corporation
American Hospital Supply Corporation
Baxter Healthcare Corporation
Baxter International, Inc.
Bristol-Myers Squibb Canada, Inc.
Bristol-Myers Squibb Company
Cabor Medical Corporation
CBI Medical, Inc.
a/k/a CBI Medical Electronics, Inc.
CooperSurgical, Inc.
CooperVision, Inc.
CUI Corporation
CVI Merger Corp.

CV Sub 1987, Inc.
Dow Corning Corporation
Dow Corning STI
Dow Corning Wright Corporation
Dow Corning Wright/Medical Materials
Hazelton Biotechnologies, Inc.
Hazelton Corporation
Hazelton Washington, Inc.
HRP, Inc.
Linvatec Corporation
Markham Medical Association
Markham Medical International, Inc.
Markham Surgical Specialties
Mark/M Resources, Inc.
MEC Subsidiary Corporation
f/k/a Surgitek, Inc.
Mark/M Surgical
Medical Engineering Corporation
Natural "Y" Surgical Specialties, Incorporated
Poly Plastic Silicone Products, Inc.
Sirod Corporation
Summit Medical Corporation
Surgitek, Inc.
Edward Weck, Incorporated
Edward Weck & Company, Inc.
Wright Manufacturing, Inc.
Zimmer, Inc.
Zimmer International, Ltd.

EXHIBIT B
Released Parties

ACME Engineering
Louis Argenta
Franklin L. Ashley
Baxter Acquisition Sub., Inc.
Baxter Corporation
Baxter Travenol Laboratories, Inc.
Baxter World Trade Corporation
John Beernick
Bio Manufacturing, Inc.
Bioplasty, Inc.
Laurence Birnbaum
Robert Bishop
Ralph Blocksma
Garry S. Brody
Boyd Burkhardt
Angelo Cappozzi
Thomas Cronin
Eugene Courtiss
Corning Incorporated
CVI Merger Corp.
The Dow Chemical Company
Edwards Laboratories, Inc.
Derwood Faries
Vicki Galati
Frank Garow
Ben Gregory
John Hartley
Hazelton Research Corporation
Hazelton Wisconsin, Inc.
Robert J. Heibling

Richard P. Jobs
Harold Markham
Jacqueline Markham
Lottie Markham
Anita Kost McAteer
Kathy Montgomery
Real Lappierre
W. John Pangman, II
Vincent R. Pennial
Marie Pietsch
Robert Reeder
W. Ian Rogers
Diran M. Seropian
Schulte Medical Products
H.E. Sterling
Kuros Tabari
Travenol Laboratories, Inc.
Uroplasty, Inc.
Charles Vinnick
Kurt Wagner
John L. Williams
Wright Medical Technologies

EXHIBIT C
Notice Program

The Federal Rules of Civil Procedure require that the Court direct to the members of the class the best practicable notice under the circumstances. Unlike some other class actions, in this litigation the primary Class Members

– those with breast implants – know whether they have been exposed to the products at issue, breast implants. Furthermore, this litigation has been the subject of extensive media attention over the last 18 months, with the result that most putative Class Members in this country are probably aware of the litigation if not its potential settlement. That more than 40,000 phone calls were received in the first week since Plaintiffs' Settlement Counsel established a toll-free information line demonstrates the degree of awareness among implant recipients. This Notice Program has been designed to provide, in the light of these circumstances, due and sufficient notice and satisfy the requirements of due process and Fed. R. Civ. P. 23, without wasteful diminution of settlement funds through excess notification procedures.

The Notice Program consists of several components designed to assure the maximum reasonably practicable notice to the settlement class. The purpose will be to inform the members of the class of the terms of the proposed settlement, the manner in which the settlement may effect their rights, the operative deadlines for opting out of or objecting to the settlement, and the procedure for obtaining further information and for filing claims.

The Notice Program takes into consideration the nature of the class membership (*i.e.*, age, gender, income levels, and geographic distribution of the class) and is specifically targeted to reach the maximum number of Class Members, in the United States and other countries, without undue and unwarranted expenditures. The program includes the direct mailing of a complete Notice package to known Class Members, along with an "early alert" media campaign designed (through publication of

a short form Notice, television advertisement, and a public relations effort) to inform other Class Members of the essentials of the Settlement and the procedure for obtaining detailed additional information that will assist them in evaluating their rights and options. The components of the Notice Program are summarized below:

1. Individual Notice. All Class Members whose names and addresses are known or can be determined through reasonable effort will receive a Notice package by first class mail. The package will consist of a Settlement Notice that describes in detail the terms of the proposed settlement and the rights and options of Class Members, a "question and answer" booklet that answers in simple language the most common questions about the settlement, and the registration, claim, and exclusion forms. The full Notice is a combination notice under Fed. R. Civ. P. 23(c) and (e) and advises the class members of:

- the proposed class action and the proposed Settlement
- the procedures for opting out of the class
- the effect of remaining in the class
- the process for obtaining a copy of the Settlement Agreement
- the procedures for registration and filing claims.

Plaintiffs' Settlement Counsel have established a toll-free telephone information line that Class Members may call to request the Notice package and a post office box to which Class Members may write to request a Notice package. The telephone number and the post office box address will be disseminated through advertisements and a public relations effort as described below.

2. Notice by Publication/Advertisements in Print and Broadcast Media. Advertisements will be placed in various newspapers and magazines in the media markets throughout the United States that should reach the virtually all potential members of the class within the United States. The advertisements will advise potential Class Members of the proposed class action and settlement, explain the essential terms of the settlement, outline the procedures and deadlines for opting out, inform Class Members as to critical dates in the settlement approval process, and advise Class Members how to obtain detailed information about the Settlement (*i.e.*, the full Notice package). In some publications it may be more appropriate to publish an abbreviated notice merely informing Class Members of the existence of the proposed settlement and the procedure for obtaining the full Notice package. Advertisements also will be placed on local and network television stations, informing Class Members of the proposed settlement, the fact that they must act by a court-established deadline to preserve their rights, and how to obtain the full Notice package.

3. Public Relations and Education. A media outreach effort will be conducted to educate the breast implant population about the settlement. Press conferences will be held to announce the Settlement. A press kit will be distributed to major U.S. newspapers and a video news release will be distributed to the television media regarding the settlement. The press conferences and distribution of press materials and news releases are intended to generate further media coverage that will provide information to Class Members of their basic rights and options under the settlement and instruct

Class Members how to obtain additional information and the full Notice package. This segment of the Notice program may include the preparation and distribution of "radio actualities" (interview quotes that radio stations can use as part of newscasts).

4. Direct Marketing/Communications with the Medical Establishment and Support Groups/Communications with Courts and Lawyers. The medical community has regular contact with the implant population and is therefore an important resource for dissemination of information to the Class Members. Copies of a short form notice and an explanatory letter will be mailed to appropriate medical groups and members of the medical community. Concise informational materials will be mailed to various professional organizations and interest groups that will in turn be able to inform Class Members of the proposed settlement and how to obtain the full Notice package. In addition, a short form notice and an informational letter will be distributed to all state courts in which cases have been filed and to lawyers and/or associations of lawyers that may have clients affected by the settlement.

5. On-Line Computer Networks. The Notice program will take advantage of computer network services in a further effort to inform Class Members of the settlement and their rights. The program will establish bulletin boards and discussion groups on the leading networks and through those avenues will inform the Class Members of their basic rights and obligations under the proposed settlement and the procedure for obtaining the full Notice package.

6. Foreign Communications. Foreign Class Members will be informed of their rights under the settlement and of the deadlines that will affect their rights to opt out of and to participate in the settlement. Identified Foreign Class Members will receive the full Notice package by direct mail in the same manner as United States Class Members. In addition, a media campaign will inform the non-U.S. Class Members of the essential terms of the Settlement (including the rights and options of the class members) and the procedures for obtaining the complete Notice package. The campaign will consist of distribution of press materials to selected press corps and reporters, press conferences in selected foreign cities, placement of advertisements in selected newspapers, and the distribution of informational materials to targeted medical groups and health agencies (subject to the requirements of various foreign governments). It should be noted that should foreign claimants (whether because of not receiving notice or for other reasons) fail to exercise their rights to opt out, to register for benefits, or file claims, they would not be precluded from pursuing any remedies they may have in the country in which their breast implants were implanted.

7. Agents. The Notice program will be implemented by APCO Associates, Inc. under the supervision and jurisdiction of the Court. Details concerning the total cost of the Notice program and the fees to be paid to APCO will be the subject of a separate order to be entered at a later date.

UNITED STATES DISTRICT COURT –
NORTHERN DISTRICT OF ALABAMA
OFFICIAL COURT NOTICE

Breast Implants Products Liability Litigation,
MDL No. 926

ATTENTION

ALL PERSONS WHO HAVE EVER
HAD BREAST IMPLANTS
and their estates, representatives, spouses,
children, and other relatives

PROPOSED BREAST IMPLANT SETTLEMENT

Lawsuits seeking damages for injuries allegedly resulting from breast implants are pending in many state and federal courts. Federal lawsuits are coordinated in the United States District Court for the North District Alabama, before Chief Judge Sam C. Pointer, Jr., as *in re Silicone Gel Breast Implants Products Liability Litigation.* Case No. CV 92-P-10000-S. One of the federal cases, *Lindsey, et al. v. Dow Corning Corp., et al.*, Case No. CV94-P-11558-S, has been conditionally certified as a class action for purposes of a proposed settlement on behalf of persons who may now or later have claims against certain manufacturers of breast implants and suppliers. This settlement includes all breast implants containing silicone, silicone gel, or saline, but does not include silicone injections.

At your written or phone request, you will receive the detailed Breast Implant Litigation Settlement Notice ("Settlement Notice") describing a proposed settlement under which certain manufacturers of breast implants and their suppliers have agreed to pay up to

$3,726,820,000, as needed under the settlement, to receive current and future claims against them. Payments will be made by the settling defendants during a 30-year period into a "Disease Compensation Program" and a series of special "Designated Funds" for the benefit of Class Members. An earlier settlement with the Mentor companies and reorganization of the Bioplasty companies will add approximately $30,000,000 to the settlement funds.

- The Disease Compensation Program has two parts. The "Current Disease Compensation Program" will provide direct compensation to those Class Members who timely make claims for certain defined existing diseases or medical conditions; the "Ongoing Disease Compensation Program" will provide direct compensation to such Class Members not timely filing their claims and to Class Members who during the next 30 years develop one or more of those diseases. The projected net compensation (after reduction for all administrative costs and legal fees) to Class Members with these diseases under either program ranges from $105,000 to $1,400,000, depending on the disease, level of severity or disability, age when first manifested and pre-existing conditions. The Settlement Notice describes the covered diseases, the projected compensation amounts (and the conditions under which these amounts may be increased or decreased), and the procedures for making and documenting claims. The settlement does not require proof that a covered disease was caused by a breast implant.

- The Designated Funds will provide compensation or reimbursement for Class Members' medical evaluations, expenses for removal of Implants ("explantation"). Implant ruptures, and other injuries or emotional distress not constituting a covered disease under the Disease Compensation Program, and for

payment of all administrative expenses and legal fees incurred in the settlement, in claims administration, and in the handling of individual claims.

FAIRNESS HEARING

Judge Pointer will hold a hearing in the United States Courthouse, 1729 Fifth Avenue North, Birmingham, Alabama, on August 18, 1994, at 9:00 a.m. to determine whether the proposed settlement is fair, reasonable, and adequate and should be approved. You do NOT need to attend the hearing. You may comment by mail as this notice explains.

WHO IS A CLASS MEMBER

Except as noted below, the Settlement Class includes

- all persons who have been implanted with one or more breast implants before June 1, 1993 (whether or not later removed)
- all children of such Class Members born after a breast implant and before April 1, 1994, who may now or later have claims for their own personal injury resulting from their mother's breast implants
- all other persons or entities (including estates, representatives, spouses, children, relatives, and "significant others") who, because of a personal relationship with such Class Members, may now or later have claims (such as for loss of services) based on injuries to such Class Members.

Class membership includes all such persons, whether or not they have brought their own lawsuit, whether or not

they are members of (or have excluded themselves from another class action, and whether or not they now suffer from a medical condition associated with a breast implant.

The Settlement Notice describes conditions under which some persons may be excluded from class membership because they have received compensation or reimbursement as a result of settlement, as a result of a judgment in federal or state court, or under the laws or procedures of another country, or because after a trial a final judgment has been rendered against them in favor of a settling defendant.

Also concluded at the present time are persons all of whose breast implants can be identified as having been manufactured or distributed by McGhan Medical Corp., INAMED Corporation, Minnesota Mining and Manufacturing Co. ("3M"), Porok Medical Technologies Corp. (or related companies), or by Kakon Co., Ltd. or other foreign manufacturers, (These companies are met currently parties to the settlement. The Settlement Notice describes circumstances, including the possibility that one or more of them might later become parties to the settlement, under which eligibility to participate in the settlement may be extended to persons with implants manufactured by those companies.)

YOUR RIGHTS AND OPTIONS

Participation in the settlement class is optional, not mandatory, if you come within the class definition, you will automatically be a class member unless you exclude yourself and your family members from the class ("opt

out"). To opt out, you must complete and return an "Exclusion Form," postmarked no later than June 17, 1994.

- If you opt out, you will NOT receive any benefits under the settlement. You would be free to file or pursue breast implant claims against all persons and companies in your own lawsuit at your own expense. Statutes of limitation or repose may limit the time for filing such lawsuits; any tolling of these periods due to pendency of a federal class action would cease 30 days after you opt out.

- If you remain in the class (by not opting out), you may make a claim to all benefits for which you are eligible under the settlement. You would give up any present or future claims against the settling defendants, subject to later opt out rights. You would retain any rights to file lawsuits against non-settling manufacturers and suppliers and against doctors, hospitals, and other health-care providers, subject to applicable statutes of limitation or repose.

TO RECEIVE SETTLEMENT NOTICE, FORMS, AND MORE INFORMATION

To make sure you receive the Settlement Notice (including details concerning the Disease Compensation Program and Disease Compensation Schedule, and the Claim, Registration, and Exclusion Forms) as well as future notices concerning the settlement, complete and return the attached information Request Form, or call the 24-hour Settlement Information Line, 1-800-557-6828 (toll-free U.S.) or 318-609-8600, without delay. Your request will not be a matter of public record and your identity will be protected against disclosure except to the extent

necessary to administer the settlement. The Settlement Notice and Forms will be mailed to you by April 18th (or within 5 days after your request), and in the interest of privacy will show the sender as "MDL 926."

TO MAKE A CLAIM OR REGISTER FOR FUTURE CLAIMS

To make a claim under the Current Disease Compensation Program, you must complete and return a Claim Form, with any necessary supporting documents, postmarked no later than September 16, 1994. To preserve your right to make claims under the Designated Funds or under the Ongoing Disease Compensation Program, you should complete and return a Registration Form, postmarked no later than December 1, 1994.

LATER OPT OUT RIGHTS

Persons who remain in the class will have additional opportunities so opt out at a later date if the projected compensation amounts payable for covered disease under the Disease Compensation Program may be reduced because the available funds are insufficient to pay the full amount of the claims approved under the Program. Should such a reduction occur during processing of Current Disease claims, persons electing at that time to opt out would be entitled to pursue all individual damages claims, including punitive and statutory multiple damages, against the settling defendants. Should such a reduction occur during processing of Ongoing Disease claims, persons electing at that time to opt out would be entitled to pursue individual claims for all damages,

except punitive or statutory multiple damages, against any or all settling defendants. The Settlement Notice describes additional opt out rights afforded to Class Members who are the children of breast implant recipients, with respect to claims of their own personal injury resulting from their mother's breast implants.

TO COMMENT ON OR OBJECT TO THE SETTLEMENT

Class members who do not opt out may comment in support of or in objection to the proposed settlement. To be considered, written comments or objections must be postmarked by June 17, 1994, and mailed to:

MDL 926
P. O. Box 11683
Birmingham, AL 35202-1683

REPRESENTATION BY COUNSEL

You may retain an attorney of your choice. You are not, however, required to have a private lawyer in order to comment on the settlement or make a claim, and Settlement class Counsel designated by the court will automatically represent Class Members who do not have their own lawyers. Class counsel support the settlement and will assist you in the settlement claims process at your request. All fees and expenses of attorneys (whether court-appointed or individually-retained) are subject to court approval and are to be paid from the Designated Fund established for that purpose, rather than from the other Designated Funds or from the Disease Compensation Program. The court has indicated that no more than 25% of the total settlement should be used to pay fees and

expenses of attorneys and the cost of notice and claims administration. Because all legal expenses will be paid from this special Fund, the amount of money you receive will not be affected by whether or not you have a lawyer. The Settlement Notice contains further details concerning attorneys' fees and costs.

THIS NOTICE HAS BEEN APPROVED BY:

Sam C. Pointer, Jr.
United States District Judge

INFORMATION REQUEST FORM
Please send me the Settlement Notice with
Registration, Claim, and Exclusion Forms

Name: _____
Telephone Number: ( ) _____
Address: _____
_____
_____

Type or Print Legibly and Mail To:

MDL 926
P. O. Box 11683
Birmingham, AL 35202-1683

ROBERT J. DEBRY & ASSOCIATES
ROBERT J. DEBRY, Esq. (A #0849)
KAREN M. THOMAS, Esq.
SAMUEL D. THURMAN, Esq., Of Counsel
WALLACE R. BENNETT, Esq. (A #0286) Of Counsel
4252 South 700 East
Salt Lake City, UT 84107
Telephone: (801) 262-8915

FRANK E. MOSS, Esq. (A #2337) Of Counsel
HALEY & STOLEBARGER
175 South Main #1000
Salt Lake City, UT 84111
Telephone: (801) 531-1555

D. FRANK WILKINS, Esq. (A#3468), Of Counsel
BERMAN & O'RORKE
50 South Main, #1250
Salt Lake City, UT 84144
Telephone: (801) 328-2200

DAVID D. BENNETT, Esq. (A #5917)
SCIENCE & LAW RESEARCH INSTITUTE
633 South 800 East
Salt Lake City, UT 84102
Telephone: (801) 521-4065

Attorneys for Plaintiffs

IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, et al., Plaintiff, vs. McGHAN MEDICAL CORP., et al., Defendants.	MOTION FOR CLASS CERTIFICATION OF COUNTS XII, XIII, AND XIV Local Case No. 92-C-0889J MDL Case No. Judge Bruce S. Jenkins

Pursuant to Rule 23(c)(1) and 23(c)(4)(A) Federal Rules of Civil Procedure, plaintiffs respectfully move for an order that Counts XII, XIII, and XIV of this complaint be certified to proceed as a class action.

In support of this motion, plaintiffs rely on the memorandum of law filed herewith.

DATED this 28th day of October , 1992.

ROBERT J. DEBRY &
ASSOCIATES
Attorneys for Plaintiff

By: /s/ Robert J. Debry
ROBERT J. DEBRY

ROBERT J. DEBRY & ASSOCIATES
ROBERT J. DEBRY, Esq. (A 0849)
KAREN M. THOMAS, Esq.
SAMUEL D. THURMAN, Esq., Of Counsel
WALLACE R. BENNETT, Esq. (A 0286) Of Counsel
4252 South 700 East
Salt Lake City, UT 84107
Telephone: (801) 262-8915

FRANK E. MOSS, Esq. (A 2337) Of Counsel
HALEY & STOLEBARGER
175 South Main #1000
Salt Lake City, UT 84111
Telephone: (801) 531-1555

D. FRANK WILKINS, Esq. (A 3468), Of Counsel
BERMAN & O'RORKE
50 South Main, #1250
Salt Lake City, UT 84144
Telephone: (801) 328-2200

DAVID D. BENNETT, Esq. (A 5917)
SCIENCE & LAW RESEARCH INSTITUTE
633 South 800 East
Salt Lake City, UT 84102
Telephone: (801) 521-4065

Attorneys for Plaintiffs

IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, et al., Plaintiff, vs. McGHAN MEDICAL CORP., et al., Defendants.	MEMORANDUM IN SUPPORT OF MOTION FOR CLASS CERTIFICATION RESPECTING COUNTS XII, XIII, AND XIV Local Case No. 92-C-0889J [Related to MDL Docket No. 926] Judge Bruce S. Jenkins

FACTS

Plaintiffs are women who have received silicone gel breast implants. Although asserting three distinctive legal theories, the factual background of this newly filed case is substantially similar with or identical to all other cases which have been consolidated to the Federal District court in Birmingham, Alabama pursuant to MDL Order No. 926.

PROCEDURAL STATEMENT

The case of *Donna Dante v. Dow Corning et al.* has previously been certified to proceed as a nationwide class action. (See Exhibit A.)

For the most part, this case (*Albrecht*) is a carbon copy of the *Dante* case. In fact, Counts I through XI of the *Albrecht* case are virtually word-for-word identical to the Complaint which was certified as a class action in *Dante*.[1] However, Counts I through XI of *Albrecht* are all pleaded as individual claims while those same claims are pleaded as class claims in *Dante*. (Thus, the plaintiffs in *Albrecht* would "opt out" of the *Dante* class action.) Counts XII and XIII of the *Albrecht* Complaint break new ground, and do not appear in any form in the cases consolidated under the MDL umbrella.[2] These Counts are pleaded as a

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[1] After Judge Rubin certified the class in *Dante*, the Complaint was amended to add new theories. It is not clear whether those additional theories are included under the class action umbrella as certified by Judge Rubin.

[2] Count XII is a claim for common law battery. County XIII is a claim asserted under universal humane principles established in the Nuremberg War Code (adopted by the United Nations as international law). Count XIV will not be separately

nationwide class action pursuant to Rule 23(c)(4)(A) F.R.C.P.[3]

POINT I

MOST OF THE REQUIREMENTS FOR CLASS CERTIFICATION HAVE ALREADY BEEN ESTABLISHED

As noted in the Procedural Statement above, a virtually identical class action has already been certified with respect to parallel counts I-XI, in the case of *Donna Dante v. Dow Corning, et al.* (See Exhibit A.) The *Dante* court has already made implicit factual determinations respecting numerosity (Rule 23(a)(1)), commonality (Rule 23(a)(2)), typicality (Rule 23(a)(3)), and superiority (Rule 23(b)(3)).

Under principles of res judicata, or collateral estoppel, or law of the case, it should not be necessary to relitigate these questions in this context.

The doctrine of collateral estoppel is subject to a multi-part test. If this standard is met, it operates to put a particular issue or issues to rest as a matter of law. The test requires: first, "the issue must have been actually litigated" (i.e., contested and submitted for judicial determination); second, "the issue must have been actually

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considered further herein but is based on the Magnusson-Moss Warranty Act. These class action counts are against Dow Corning only.

[3] "When appropriate . . . an action may be brought or maintained as a class action with respect to particular issues." Compare § 30.17 *Manual for Complex Litigation Second.*

and necessarily determined by a court of competent jurisdiction" in a prior trial; third, "preclusion in the second trial must not work an unfairness." *Johns v. Rozet*, 141 F.R.D. 211, 1992 U.S. Dist. LEXIS 1109, 5-6 (D.D.C. 1992) (citing *Jack Faucett Associates, Inc. v. AT&T*, 744 F.2d 118, 125 (D.C. Cir. 1984), cert. denied 469 U.S. 1185). *See also, Cotton States Mutual Ins. Co. v. Anderson*, 749 F.2d 663, 666 (11th Cir. 1984) (quoting *Williams v. Bennett*, 689 F.2d 1370, 1381 (11th Cir. 1982) (listing the three elements of the collateral estoppel test). Other courts break down the elements of collateral estoppel into four parts:

> (1) the issue sought to be precluded must be the same as that involved in the prior action; (2) the issue must have been actually litigated to final judgment; (3) the determination must have been essential to the final judgment; and (4) the party against whom estoppel is invoked must have been fully represented in the prior action.

In re Tom Livaditis, 122 Bankr. 330, 334 (Bankr. N.D. Ill. 1990) (citing *Klingman v. Levinson*, 831 F.2d 1292, 1295 (7th Cir. 1987)). The tests are identical in substance. Collateral estoppel will thus not apply if the three or four pronged test is not satisfied, such as situations where a district court's ruling is "avowedly tentative." *See In re Tom Livaditis, supra* at 335 (citing cases applying this exception).

Class certification has, itself, been expressly considered as an issue subject to collateral estoppel in several cases. In *Johns v. Rozet, supra*, the court agreed with the plaintiffs that the "Superior Court's previous class certification bars relitigation of the issue [of class certification] under the doctrine of issue preclusion." In *In re Tom Livaditis, supra*, the bankruptcy court ruled that the prior

order of the district court ordering class certification must be given preclusive effect in a subsequent action since the elements of collateral estoppel were satisfied. In *Lee v. Williamson*, 659 F.Supp. 813, 821 (S.D. Ga. 1987), the court observed, quoting *McLaughlin v. Bradley*, 602 F.Supp. 1412, 1417 (D.D.C. 1985): "Sanctions are especially appropriate in situations were [sic] the doctrines of res judicata and collateral estoppel plainly preclude relitigation of the suit." also cited was *Robinson v. National Cash Register Co.*, 808 F.2d 1119 (5th Cir. 1987).

Collateral estoppel essentially hinges on whether the same issue of "ultimate fact" was previously litigated, and is, primarily, a factual question. The issue may pertain to mixed questions of law or fact, or even to "pure questions of law if the claims stem from the same transaction or if injustice will otherwise result." *Romano v. Kimmelman*, 464 A.2d 1170, 1175 (N.J. Super. Ct. App. Div. 1983). *See also Bastian v. Petren Resources Corp.*, 681 F.Supp. 530, 535 (N.D. Ill. 1988) ("The fact that the [prior] decision [denying certification] was based on nearly identical questions of fact and law, and was affirmed by the Third Circuit, mandates that this court give it deference here." (Citing *Premier Elec. Const. Co. v. NERC*, 814 F.2d 358, 367 (7th Cir. 1987); *Colby v. J.C. Penney Co.*, 811 F.2d 1119, 1123-24 (7th Cir. 1987).

In summary, it is not necessary to relitigate the factual basis for class certification since the essential facts have already been litigated in the *Dante* case.

POINT II

THE REQUIREMENTS OF RULE 23(a) (4) (ADEQUATE REPRESENTATION) ARE MET

In order to certify a class action, a court must determine that, "the representative parties will fairly and adequately protect the interests of class members." Rule 23(a)(4). Courts look primarily to the qualifications of class counsel – not to the named plaintiffs – to determine whether the class will be adequately protected under Rule 23(a)(4):

> The single most important factor considered by the courts in determining the quality of the representatives ability and willingness to advocate the cause of the class has been the caliber of the plaintiff's attorney.

The Class Representative: The Problem of the Absent Plaintiffs, 68 NW UL Rev. 1133, 1136 (1974); *see also, Newberg on Class Actions* at § 3.24.

Notwithstanding the effects of collateral estoppel in other respects (Point I above), it is necessary to consider Rule 23(a)(4) because a different team of attorneys is proposed to manage Counts XII, XIII and XIV of the *Albrecht* class action.

The qualifications of the *Albrecht* class counsel may be summarized as follows:

> Robert J. DeBry will serve as lead trial counsel. Robert J. DeBry has been awarded a certificate of special competence in Civil Trial Advocacy by the National Board of Trial Advocacy. He is especially experienced in litigating silicone issues. *See, Celia Anderson v. The American Society of Plastic & Reconstructive Surgeons*, 807 P.2d 825

(Utah 1990) and *Anderson v. Department of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). Mr. DeBry is also experienced in class litigation. *See, e.g., Madsen v. Prudential Federal Savings & Loan Assoc.*, 635 F.2d 797 (10th Cir. 1981).

Samuel D. Thurman is now of Counsel to the firm of Robert J. DeBry & Associates. Mr. Thurman is a nationally known expert on torts and has served as an advisor on the Restatement (Second) of Torts for many years. For over a decade, Mr. Thurman was Dean of the University of Utah Law School. Mr. Thurman is listed in "Who's Who" and "Who's Who in American Law." He has authored many nationally recognized textbooks.

Wallace R. Bennett is Of Counsel to the firm of Robert J. DeBry & Associates. Mr. Bennett is Professor of Law Emeritus and was Associate Dean of the University of Utah College of Law. Mr. Bennett is former Commissioner on Uniform Laws, and has experience with current multistate class litigation. He holds an L.L.M. degree from Harvard University School of Law and an L.L.M. degree from New York University School of Law.

Frank E. Moss is Of Counsel to the firm of Haley & Stolebarger. Mr. Moss is a former prosecuting attorney and was the ranking United States Senator who co-authored the Magnuson-Moss Consumer Products Warranty Act, 15 U.S.C. § 2301 *et seq.*

D. Frank Wilkins is Of Counsel to the firm of Berman and O'Rorke. Mr. Wilkins is a former trial court judge and a former Justice of the Utah Supreme Court.

David D. Bennett holds an Honors Chemistry degree from the University of Utah and a Masters degree from the Department of Cellular, Viral and Molecular Biology at the Medical School of the University of Utah. He has published in scientific journals and practices law, consulting with law firms in science-related matters.

Karen M. Thomas is a Registered Nurse in addition to being a licensed attorney. She holds both an associate degree and a Bachelor of Science Degree in nursing. She possesses a varied health care background having worked as an operating room nurse for a plastic surgeon who performed breast surgery before attending law school, to serving as in house counsel for two different hospital corporations before entering private law practice.

See Complaint at paragraph 73.

POINT III

CONSIDERATIONS OF POLICY AND JUDICIAL ECONOMY SUPPORT CERTIFICATION OF THIS SEPARATE CLASS

There are a number of policy considerations which support expedited certification of the *Albrecht* sub-class for Counts XII and XIII.[4] These are:

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[4] These same policy considerations are also relevant under the rubric commonly referred to as "superiority" under Rule 23(b)(3). However, as described below, this case can be certified without reference to Rule 23(b)(3).

A. Early Trial

The continuing battery claim (Count XII) and the claim based on the Nuremberg Code (Count XIII) are ready for immediate trial. Plaintiffs' counsel do not require a pre-trial discovery beyond the evidence and data already available in the public domain. Dow Corning may wish to depose plaintiffs' experts, but that could be accomplished in a matter of weeks. (Indeed, Dow Corning has already deposed these very experts in several different cases.)

B. Simplification of Issues – Causation

Far and away the most difficult tort issue in breast implant cases is customarily "causation." That is, did the silicone gel *cause* the injury. (viz. scleroderma, systemic lupus erythematosus, rheumatic diseases, human adjuvant disease, etc.) Plaintiffs have won some of these cases, but have also lost other cases on causation grounds. (See Exhibit B.) Most cases under the MDL umbrella will require extensive pre-trial discovery relating to causation. However, causation is simply not an issue in the claims for a continuing battery (Count XII) and unlawful human experimentation (Count XIII) of the *Albrecht* case.

C. Simplification of Issues – Battery[5]

Count XII pleads a claim for common law battery. The generic simplicity of this ancient tort has important relevance to this case. The unadorned requirement to establish battery is merely an offensive contact. See generally, *Restatement (Second) of Torts* §§ 13-20.

In order to establish battery, plaintiffs need not show any particular causation or injury. Section 15 of the Restatement gives the following example of a battery:

> A has a wart on his neck. His physician, B, advises him to submit to an operation for its removal. A refuses to do so. Later A consents to another operation, and for that purpose is anesthetized. B removes the wart. The removal in no way affects A's health, and is in fact beneficial. A has suffered bodily harm.

The *Albrecht* Complaint alleges that Dow Corning had knowledge of certain dangers and defects in the silicone gel breast implant; and that, Dow Corning failed to disclose such defects. Therefore plaintiffs assert that any consent given by women for the implants was vitiated by reason of material nondisclosures and misleading representations. Section 892B of the Restatement (Second) of Torts gives the following example of a failure to disclose material facts:

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[5] This line of reasoning is not intended to prove that a multiple party battery has in fact occurred. That must wait for trial. However, this section will demonstrate that the theory of common law battery is ideally suited to breast implant litigation; and for the vast majority of women, battery would be a theory of choice.

> A gives B a vile tasting medicine to drink. A knows that the medicine is poisonous and that B does not know it. A is subject to liability to B for battery.

Since the breast implant is still in the body of most plaintiffs, the battery continues. Because the battery continues to this day, no statute of limitations forecloses the claim. *See e.g., Parker v. Vaughn,* 183 S.E. 2d 605 (GA. App. 1971).

The basic measure of damages is simply the cost of ending the battery (i.e., removing the breast implant). There may also be other damages; however, the basic cost of removing the implant will set baseline damages for all plaintiffs.

D. Simplification of Issues – Nuremberg Code[6]

Basic ethical standards for all human experimentation were declared in the Nuremberg War trials. In those momentous cases, Nazi doctors were accused of various atrocities. The doctors' defense was that they were simply conducting experiments that could be beneficial for mankind. The tribunal declared that all mankind should be

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[6] The purpose of this section is not to prove that violations of the Nuremberg Code have occurred. That must wait for trial. However, this section will demonstrate that the Nuremberg Code is an appropriate legal theory and standard for breast implant cases. Every woman who has received a silicone gel breast implant was insufficiently informed and therefore, as a practical matter, became an unwilling participant in what has become a human experiment of staggering scale.

subject to limitations when individuals are used for experimentation.

By these precepts, sixteen of twenty-three defendants were found guilty of crimes against humanity. See, *United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal* Vol. I & II, The Medical Case. Washington D.C.: U.S. Government Printing Office (1948).

The United Nations General Assembly unanimously adopted a resolution on December 11, 1946 affirming the "principles of international law recognized by the charter of the Nuremberg tribunal and the judgment of the tribunal." It has been said to be an "inescapable conclusion that the code is part of international law. . . . " Annas, *The Law of Informed Consent to Human Experimentation: Preliminary Report Prepared for the National Committee for the Protection of Human Subjects of Biomedical Research.*

The Nuremberg Code can properly be regarded as a basic ethical standard for all human experimentation, and has been used by other courts as a standard of care in the field of human experimentation. *See e.g.*, Curran, *Legal Codes in Scientific Research Involving Human Subjects*, 3 LEX ET SCIENTA 65 (1966); *Whitlock v. Duke University*, 637 F. Supp. 1463, 1470 (M.D. N.C. 1986); *Kaimowitz v. Department of Mental health for the State of Michigan*, Mental Disability L. Rep. 147 (Mich. Cir. Ct. 1983).

In the case of *United States v. Stanley*, 483 U.S. 669 (1987) a discharged serviceman sued his former superiors for causing LSD to be administered to him without his knowledge or consent during Army experimental tests. The majority opinion held that because of his military status at the time he was given LSD, Stanley could not

sue. In a scathing dissent, Justice Brennen complained that the court should not apply precedent which prevented a soldier from suing superior officers for constitutional violations. According to Justice Brennen there should be no immunity for violation of the tenets of the Nuremberg Code. Justice Brennen stated that the Code applies to "all citizens." 483 U.S. at 687. Justice O'Connor in her dissent stated that in her opinion, the constitutional guarantee of due process of law guarantees the right to seek redress for a violation of the principles of the Code of Nuremberg. 483 U.S. at 710. It seems tolerably clear that the Nuremberg Code would certainly apply in non-military cases.

The Nuremberg Code explicitly provides that:

> The voluntary consent of the human subject is essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

* * *

> The experiment should be so designed and based upon the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

Nuremberg Code at paragraphs 1 and 3.[7]

Plaintiffs' Complaint emphatically alleges that adequate animal tests were not conducted; and that Dow Corning did not reveal all of the known risks and side effects to women who received the breast implants. In effect, the approximate 1,000,000 women who received breast implants became, without their knowledge or real consent, subjects of mass human experimentation. (See Exhibit D.)

Finally, the Code itself indicates an appropriate remedy:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

Nuremberg Code at paragraph 9.

Under this universal concept, a mandatory affirmative injunction should issue requiring Dow Corning to inform all recipients of Dow Corning breast implants of the known risks and side effects. After being fully informed, each woman should have an opportunity, at her election, to bring the experiment to an end by having the implants removed at Dow Corning's expense.

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[7] The entire Nuremberg Code is attached at Exhibit C.

E. Prevention

The existing class action (*Dante*) is well suited to compensate women who have been physically injured through use of a breast implant. However, the *Dante* class action does little to assist women who can not yet show that they have sustained demonstrable injury.

The continuing battery and the Nuremberg Code concepts provide compensable bases for past injuries *and* are remedial vehicles for preventing future injuries. The battery and the Nuremberg Code theories provide grounds for removal of breast implants *before* further injury occurs. This judicially declared redress would be in the nature of a nationwide recall.

Since the beginning of time, the law has valued prevention of injury over mere payment for past injury. Thus, an ancient Latin maxim reads: *Praestat cautela guam medela* ("Causation or prevention is better than cure"). Another maxim is of like kind: *Le salut du peuple est la supreme loi* ("The safety of the people is the supreme law."). Mr. Justice Cardozo stated: "The final cause of law is the welfare of the society. The rule that misses its aim cannot permanently justify its existence." *The Nature of Judicial Process,* 66 (1921). In the case of *NLRB v. Robbins,* 437 U.S. at 239-40, the court instructed: "[The] possibility of deference arising from post hoc disciplinary action is no substitute for a prophylactic rule that prevents the harm. . . . "

F. Limited Funds and the 23(b)(1)(B) Class

The *Dante* case was certified under Rule 23(b)(3). The *Albrecht* case also qualifies for 23(b)(3) treatment. However, in addition, *Albrecht* also meets the requirements of Rule 23(b)(1)(B).[8]

Rule 23(b)(1)(B) is especially suited to limited fund cases. See *Newberg on Class Actions*, § 4.09. The *Dante* class action raises the distinct *possibility* of a limited fund case.[9] The *Albrecht* class action makes it a virtual certainty that Dow Corning's fund of corporate assets and insurance will not be adequate to the totality of the compensable claims presented.

G. Injunctive Relief and the 23(b)(2) Class

The Court may fashion relief, in part, in the form of a mandatory injunction that Dow Corning end the continuing battery and unlawful human experimentation. Such injunctive relief would support certification under Rule 23(b)(2). See *Newberg on Class Actions*, § 4.11.

H. Notice

If the *Albrecht* case is certified under Rule 23(b)(1)(B) or under 23(b)(2), no notice is necessary. *Newberg on Class Actions*, § 8.05.

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[8] Class actions that qualify for class certification under 23(b)(1)(B) should not normally be certified under 23(b)(3). See *Newberg on Class Actions*, § 4.20

[9] Some fact finding is necessary to prove the limited fund. *In re Bendectin Products Liability Litigation*, 749 F.2d 300 (6th Cir. 1984).

Nevertheless, since a notice has already been sent out in the *Dante* case, the court may yet have an occasion to order that an amended notice be sent. In any amended notice, it would be easy to disclose the alternative concepts of the *Albrecht* (b)(1)(B) and (b)(2) classes.

CONCLUSION

In addition to the existing (*Dante*) class actions, this court should expeditiously certify at least two additional causes of action: battery and claims based on Nuremberg Code. Certification of these additional claims would give the vast majority of women with breast implants an opportunity to have those implants removed before a disease process begins or continues detrimentally.

DATED this 25th day of October, 1992.

ROBERT J. DEBRY &
ASSOCIATES
Attorneys for Plaintiff

By: /s/ Robert J. Debry
ROBERT J. DEBRY

By: /s/ Wallace R. Bennett
WALLACE R. BENNETT

By: /s/ Samuel D. Thurman
SAMUEL D. THURMAN

By: /s/ D. Frank Wilkins
D. FRANK WILKINS

By: /s/ Frank E. Moss
FRANK E. MOSS

By: /s/ David Bennett
DAVID BENNETT

Law Offices

Robert J. DeBry & Associates

4252 South 700 East
Salt Lake City, Utah 84107
(801) 262-8915
Fax 801-262-8995
Toll Free 800-232-8915

Robert J. DeBry
G. Steven Sullivan
Warren W. Driggs
George T. Waddoups*
Edward T. Wells
Glen A Cook
J. Jordan Christianson
Karen M. Thomas**

Of Counsel
Wallace R. Bennett

*Also Admitted in Idaho
**Also Admitted in Kentucky and Mississippi

West Valley Office
3575 South Market St.
Suite 206
West Valley, Utah 84119
(801) 966-8111
Fax 801-966-8092

Ogden
(801) 479-7848

Provo
(801) 224-9447

St. George
(801) 628-7787

May 11, 1993

Honorable Sam C. Pointer
U.S. District Court
Northern District of Alabama
U.S. Courthouse
Birmingham, AL 35203

Dear Judge Pointer:

We have received a copy of a letter from Dow Corning's attorney (Dr. Frank Woodside) in response to our "Urgent Request to Set Hearing Date in the case of *Albrecht v. McGhan Medical, et al.* (92-P-11104-S)." Dr. Woodside's letter references a hearing of January 22, 1993,

when the Court apparently made a bench ruling regarding the *Albrecht* case.

We must apologize to the Court that we were not in attendance at that hearing to respond to questions or otherwise assist the Court. For whatever reason, we were simply not aware (until receipt of Dr. Woodside's letter) that this matter would be called on the January 22 calendar.

However, based upon Dr. Woodside's letter, we are now aware of the Court's concern as expressed in that January 22 hearing:

> To the extent that these are appropriate claims and to the extent were [sic] going to have a class, *I can deal with it in other litigation* without the need to utilize this particular device for certain limited theories of action. (Emphasis added.) (January 22, 1993 Transcript at p. 161-162.)

If we had been present, we would have responded that the Court is absolutely correct as a *theoretical* matter. However, as a *practical* matter serious problems arise if class certification in *Albrecht* is delayed. We would have further observed that the practical problems of such delay would be especially serious in the context of settlement discussions. Thus, we would have argued as follows:

First, a partial settlement (not including the *Albrecht* claims) may deplete available assets and insurance coverage. Therefore, any later judgment in *Albrecht* may be largely meaningless.[1]

Second, a partial settlement (not including the *Albrecht* claims) would require the Court to send confusing notice of such partial settlement to class members. Further, class members, being unaware of their rights under common law battery and Nuremberg Code theories, would be confused about whether or not to opt out of the class.

Third, neither the Lead Counsel's Committee in *Dante* nor the Plaintiffs' Steering Committee in the *MDL* case can properly evaluate or negotiate claims (for battery and Nuremberg Code violations) which they have never even thought of.

Fourth, the existing *Dante* attorneys and the existing *MDL* Plaintiffs' Steering Committee seem to be doing an adequate job to protect the interests of those women with a bodily injury. However, a legitimate question might be raised whether the *Dante* and *MDL* attorneys have sufficiently protected the uninjured women. Certainly the

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[1] Assume conservatively 500,000 women in the *Albrecht* class. These would be women who have suffered no bodily injury; but who are, nonetheless, entitled to monetary damages to end the continuing battery or to end the unlawful experiment. Assume conservatively a $10,000 judgment or settlement for each of the 500,000 class members in *Albrecht*. That would yield a total judgment of *five billion dollars*! If Dow Corning still has five billion dollars left after settling *Dante*, there is no problem.

Dante and *MDL* attorneys have not even pleaded appropriate theories of relief for uninjured women. [viz. common law battery and violations of the Nuremberg Code.] Thus, the *Albrecht* complaint might be viewed as an appropriate vehicle through which uninjured women may receive proper representation as they compete against injured women for a fair allocation of the limited funds.

Again, we apologize that we were not present at the January 22 hearing; however, these additional comments (above) may assist the Court in assessing the need for a further hearing on class certification in *Albrecht*.

Sincerely,

/s/ Robert J. Debry
ROBERT J. DEBRY

RJD/vah
cc: Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

Supreme Court, U.S.
FILED
SEP 29 1994
OFFICE OF THE CLERK

(3)

No. 93-2052

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR CERTIORARI

ROBERT J. DEBRY
Counsel of Record
ROBERT J. DEBRY & ASSOCIATES
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

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SUMMARY OF ARGUMENT

In determining whether sufficient reasons exist for granting certiorari, this Court focuses on whether the presented issues are of importance to the public as distinguished from the individual concerns of the litigants. *E.g., N.L.R.B. v. Pittsburgh S.S. Co.*, 340 U.S. 498, 502 (1951).

The issue of whether the Nuremberg Code's ethical standards are encompassed within due process or federal common law is a special and important issue squarely before this Court. Moreover, as hereinafter set forth, the Nuremberg Code issues were sufficiently preserved in the lower courts.

Further, a controversy does exist among the Circuit Courts of Appeal as to when mandamus will issue to review and correct procedurally defective class action certification proceedings.

The ruling on class action certification is often the most significant decision rendered by the district court in class action proceedings.[1] *Deposit Guaranty Nat'l Bank v. Roper*, 445 U.S.

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[1]Proceedings in this case confirm the truism announced by *Roper*. After the original *Petition for Writ of Mandamus* was filed, the trial court announced a nationwide $4.3 billion settlement. *See* Appendix, A-162. The problem is that the settlement only covers women who have suffered a "personal injury." (*See* Appendix A-162 at ¶ 2(a)(1).) On the other hand, the Nuremberg Code would cover those women who are not yet injured. Specifically, the Nuremberg Code would require full disclosure of all foreseeable risks to every woman who has had a breast implant; and the Code would permit any women to withdraw from the experiment (i.e., to have explant surgery). Nothing in the current settlement requires a full disclosure of

326, 339 (1980). However, in this case, the district court provided no notice, and declined to grant a hearing on petitioners' motion to certify the class. The Court also did not make specific factual findings as required by F.R.C.P. 52(a) and as suggested by F.R.C.P. 23. The Eleventh Circuit Court of Appeals effectively rubber-stamped the district court's misconduct. Thus, this case presents the issue of whether mandamus should issue to correct the deficient class certification proceedings. It is a special and important reason for granting certiorari because the issue invokes the supervisory powers and duties of this Court.

Finally, the petition presents this Court with a unique and valuable opportunity to refine its decision in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1931). Since the *Erie* decision, no clear test has been expressed for determining whether federal common law should or will be applied to nationwide tort litigation.

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risks. *See* Appendix A-162. In short, a major purpose of the Nuremberg Code is to prevent future injury. On the other hand, the scope of the current settlement is to pay for past or future injuries.

If this *Petition for Certiorari* is not granted, no one will ever know if the settlement should have been $4 billion or $14 billion. Furthermore, countless women will not be given an opportunity to avoid injury *before* it occurs.

ARGUMENT

POINT I

WHETHER THE NUREMBERG CODE'S ETHICAL STANDARDS ARE ENCOMPASSED WITHIN DUE PROCESS OR FEDERAL COMMON LAW IS A SPECIAL AND IMPORTANT ISSUE JUSTIFYING CERTIORARI

A. The Nuremberg Code.

The Nuremberg Code's ethical standards are not, as Dow Corning characterizes them "no legal authority." In *United States v. Stanley*, 483 U.S. 669, 687 (1987), Justice Brennan, in a concerning and dissenting opinion, noted that the Code, although a product of a military tribunal, applies to both soldiers and civilians, and that "experimentation with unknowing human subjects is morally and legally unacceptable." 483 U.S. at 687. Similarly, Justice O'Connor concluded that if the voluntary consent required by the Code is violated, due process guarantees compensation. 483 U.S. at 710.

Further, the Nuremberg Code claim is a distinct legal theory and provides a unique remedy for unlawful experimentation -- termination of the experiment. A copy of the Code is in the Appendix to this reply brief. A-162, *infra*.

B. Proceedings in the Lower Courts.

When the trial court denied the petitioners' motion to certify the class, the court also rejected the Nuremberg Code as a viable legal theory. The court began by invoking laughter at the Code claim:

> THE COURT: Before you say anything, I am going to deny the motion for class certification.
>
> (Laughter.)

(Pet. App. at p. A-13.)

Next, the court expressed doubt that a Nuremberg Code claim is an appropriate claim.

> To the extent that these are appropriate claims . . . that is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory.

(*Id.* at pp. A-13, 14.)

Finally, the Court failed to acknowledge the unique nature and remedies contained in the Nuremberg Code when it ruled:

> [T]o the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action.

(*Id.* at A-14.)

However, the district court cannot deal adequately with the Nuremberg Code claim absent a class action certification. Only the petitioners pled a Code claim. Unless the complaint is certified as a class action, women will not have the benefit of the Code's ethical standards, ease of proof and unique remedy.[2] Therefore, unless the Code's universal standard of care is applied to a universal class the court cannot adequately deal with the Code.

More importantly, the laughter, the court's failure to acknowledge the Code claim, and its failure to appreciate the Code's

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[2]See footnote 1, above.

standards, ease of proof and remedy all show that the Court rejected the Code as a legal theory.[3] Further, since the rejection of the Code was tacitly approved by the Eleventh Circuit Court of Appeals when it denied the subsequent petition for mandamus, the issue of whether the Code is part of due process or federal common law is ripe for decision.

C. Why the Nuremberg Code Issue is Special and Important.

In *Erie R. Co.*, *supra*, certiorari was granted "because of the importance of the question of whether the federal court was free to disregard the alleged rule of the Pennsylvania common law. . . ." *Erie R. Co.*, *supra* at 71. Similarly, in this case, the petition presents three possibilities: (1) the Court could rule that the Code's principles are within due process; (2) the Court could rule that the Code's principles are part of the common law; or (3) the Court could conclude that a nationwide tort class action case requires a federal common law ethical standard.[4] *C.f.*, *Moragne v. States Marine Lines*, 398 U.S. 375 (1970) (holding that an

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[3] Even if the Nuremberg Code claim was not completely adjudicated in the trial court, certiorari is justified. When there were problems in the class action hearings requiring resolution, the Court may grant certiorari to resolve the class action issues prior to trial. *See Eisen v. Carlisle and Jacquelin*, 417 U.S. 156, 159 (1974) (certiorari granted to resolve questions involving petitioner's attempt to maintain his suit as a class action).

[4] The need for uniformity is the most frequently cited reason for fashioning federal common law. Annot: *The Supreme Court and the Post Erie Federal Common Law*, 31 L. Ed.2d 1006, 1014 (1972).

action lies under federal, general maritime law for death caused by a violation of maritime duties in state waters). The three possibilities illustrate just how important the special issue is. This Court has a unique opportunity to revisit and refine *Erie R. Co.*

POINT II

THIS CASE PRESENTS A CONTROVERSY AMONG THE CIRCUIT COURTS OF APPEAL OVER WHEN MANDAMUS MAY ISSUE TO REVIEW AND CORRECT DEFECTIVE CLASS CERTIFICATION PROCEEDINGS

The issue of when a Circuit Court of Appeals may issue mandamus to review and correct defective class certification proceedings is a controversial issue. The Third Circuit Court of Appeals, in *Lusardi v. Lechner*, 855 F.2d 1062 (3d Cir. 1981), ruled that mandamus is unnecessary and unavailable unless there is a clear error of law and there is no adequate, alternate remedy. The Eighth Circuit issues mandamus if the district court acts outside its jurisdiction or disregards a statute. *Schmitt v. Fuller Brush Co.*, 527 F.2d 532 (8th Cir. 1975). The Eleventh Circuit Court of Appeals, theoretically, will issue mandamus if the district court ignores notice and hearing procedural safeguards. *In re Temple*, 851 F.2d 1269 (11th Cir. 1988). However in this case, the Eleventh Circuit declined to issue mandamus. The Ninth Circuit Court of Appeals issues mandamus if the district court arbitrarily applies Rule 23 of the Federal Rules of Civil Procedure. *McDonnell-Douglas Corp. v. The United States District Court for the Central District of California*, 523 F.2d 1073 (9th Cir. 1975).

The Tenth Circuit uses mandamus to protect against excessive zeal in the grant or denial of class certification. *West v. Capitol Federal Savings & Loan Ass'n*, 558 F.2d 977, 982 (10th Cir. 1977).

The controversy among the Circuit Courts over when mandamus will issue to review a defective class certification proceeding qualifies as a special and important reason for granting certiorari.

POINT III

THE DISTRICT COURT'S DEPARTURE FROM THE USUAL COURSE OF PROCEEDINGS QUALIFIES THIS CASE FOR CERTIORARI

A. The District Court's Departure from the Usual Course of Proceedings.

The District Court's failure to hold a hearing and resolve the factual issues inherent in the motion to certify the class action was a usurpation of judicial power; hence, mandamus is warranted. (Petition for Certiorari pp. 22-23.) So was the Court's failure to make meaningful findings on each factual element contained in F.R.C.P. 23. *See Commissioner v. Duberstein*, 363 U.S. 278, 292 (1960) ("[t]here comes a point where findings become so sparse and conclusory . . . [that] such . . . findings do not constitute compliance with Rule 52's direction. . . .").

B. Petitioners Allege a Clear and Indisputable Right to Issuance of the Writ of Mandamus.

A district court's ruling on the certification issue is often the most significant decision in a class action lawsuit. *Deposit Guar-*

anty Nat'l Bank v. Roper, 445 U.S. 326, 339 (1980). Frequently, as in this case, the decision determines whether claimants with moderate claims will have access to judicial relief that otherwise would be economically unavailable by means of individual litigation. *Id.* at 339. Thus, unless it is apparent from the pleadings that the Rule 23 requirements are or are not met, the court should hold a meaningful hearing. *See also General Telephone Co. of the Southwest v. Falcon*, 457 U.S. 147, 160 (1982).

The petitioners' right to notice, a meaningful hearing, and meaningful findings springs from three sources: (1) due process; (2) F.R.C.P. 23, construed by the Courts as requiring a hearing when the factual issues of numerousity, commonality, typicality and manageability are disputed; and (3) the district court's duty to manage class action litigation. (Petition for Certiorari, pp. 20-21.) The petitioners' right to meaningful findings is mandated by F.R.C.P. 52.

In summary, petitioners alleged a clear and undisputable right to notice, a hearing, and meaningful findings. What is unresolved is the issue of whether petitioners are entitled to review of the class certification proceeding via the writ of mandamus. That this issue is a controversial, unresolved issue -- instead of a clear, undisputable issue -- does not militate against certiorari. Rather, it is a special and important reason for granting certiorari. (*See* Point II of this brief.)

POINT IV

THE PETITIONERS ARE NOT ASKING THIS COURT TO INVOLVE ITSELF IN AN AREA WITHIN THE DISTRICT COURT'S DISCRETION

Dow Corning says, "The petitioners have shown no reason why this Court should involve itself in multi-district litigation in an area within the Court's discretion." (Brief of Respondent p. 12.) But, Dow Corning fails to identify the "area of discretion." The court did not have discretion to decline notice and a hearing. *See Sirota v. Solotron Devices, Inc.*, 673 F.2d 566, 571 (2nd Cir. 1982) ("there can be no dispute that it is proper for a district court . . . to conduct hearings to determine whether the prerequisites of Rule 23 are satisfied.") Implicitly, Dow Corning concedes that a hearing was required when it says that the MDL 926 status conference "was a hearing in keeping with normal practice . . . ." (Brief of Respondent, p. 13). However, the so-called hearing was no more than a denial from the bench of the petitioners' motion to certify the class. *The petitioners were not even notified that the Court would rule on their motion to certify the class at the status conference*. For that reason, petitioners' counsel did not attend. The bench announcement was not the kind of hearing required to resolve the factual issues inherent in Rule 23, and mandated by due process.

Dow Corning also does not explain how granting certiorari would interfere with the MDL proceeding. If certiorari is granted and mandamus ordered, the lower district court will simply be

required to provide notice, a meaningful hearing and meaningful findings. That is not interference. It is due process.

CONCLUSION

The issues raised in the Petition for Certiorari are special and important issues warranting certiorari. Together, the issues involve complex, unresolved questions of Constitutional and federal common law. Moreover, the Circuit Courts of Appeals are not in agreement over when a defective class action proceedings can be reviewed and corrected via mandamus. Granting certiorari does not interfere with the lower court's discretion. Rather, the lower court's departure from the usual course of proceedings is another special and important reason warranting certiorari.

Respectfully submitted,

ROBERT J. DEBRY
Robert J. DeBry & Associates
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	
SILICONE GEL BREAST	)	Master File No.
IMPLANT PRODUCTS	)	CV 92-P-10000-S
LIABILITY LITIGATION	)	
(MDL 926)	)	
HEIDI LINDSEY, et al.,	)	
Plaintiffs,	)	
	)	
-vs.-	)	Civil Action No.
	)	CV 94-P-11558-S
DOW CORNING CORP., et al.)		
Defendants.	)	

FINAL ORDER AND JUDGMENT (Corrected)

In accordance with the findings and conclusions contained in the Opinion filed herewith, the Settlement Agreement[1]--with the modifications made in prior orders, in the Opinion, and in this Order--is determined to have been entered into in good faith, to be

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1

The Settlement Agreement means not only the initial settlement agreement filed on March 19, 1994, with its Exhibits, but also the supplemental agreements or addendums later filed with respect to Union Carbide Corporation, Union Carbide Chemicals and Plastics Company, Inc., INAMED; 3M; Applied Silicone; Wilshire Foam Products, Inc.; Wilshire Advanced Materials, Inc., and Wilshire Technologies, Inc.

non-collusive, to be reasonable, fair, and adequate, to be in the best interests of the class, and therefore is approved. Based on, subject to, and incorporating such provisions, it is hereby ORDERED and ADJUDGED as follows:

1. Heidi Lindsey and the other designated Representative Plaintiffs under Order No. 15 shall have and recover for themselves and other members of the plaintiffs' class:

(a) from Dow Corning Corporation the sum of $2,018,740,000.00;

(b) from Baxter Healthcare Corp. and Baxter International, Inc., the sum of $555,790,000.00;

(c) from Medical Engineering Corporation and Bristol-Myers Squibb Co. the sum of $1,154,290,000.00;

(d) from Minnesota Mining & Manufacturing Co. the sum of $325,000,000.00;

(e) from Applied Silicone Corporation the sum of $250,000.00;

(f) from Wilshire Technologies, Inc., the sum of $8,000,000.00;

(g) from Union Carbide Corporation the sum of $138,000,000.00; and

(h) from McGhan Medical Corp. the sum of $25,000,000.00.

2. The provisional certification of the class for settlement purposes, with certain modifications, is confirmed.

(a) Except as provided in (b), the class on whose behalf this judgment is entered consists of--

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more breast implants (whether or not already or later removed), with respect to any claim against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural mother is a person described in subparagraph (1) above and who was born after the date his or her mother had a breast implant, with respect to any claim against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her mother's having had a breast implant; and

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any claim against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in subparagraph (1) or (2) above.

(b) Excluded from the class are the following:

(1) breast-implant recipients all of whose breast implants can be identified as manufactured or distributed by Porex Medical Technologies Corp., Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B to the Settlement Notice;

(2) breast-implant recipients who, as of April 1, 1994, were not citizens or permanent resident aliens of the United States if all of their breast implantations were performed outside the United States and--

(A) they have received any compensation for breast implant injuries or expenses from a Settling Defendant under the laws or procedures of another country; or

(B) they as of April 1, 1994, resided or were domiciled in Australia, or resided or had received a breast-implant in either the Province of Ontario or the Province of Quebec, Canada, except that such persons may, on an individual and purely 'opt-in' basis, become voluntary "Foreign Claimant' members of the settlement class. To opt in, such persons must file a Registration Form with the Claims Administrator, P.O. Box 56666, Houston, Texas, USA, 77256, post-marked no later than December 1, 1994. By voluntarily opting in through this registration, such persons--

(i) will be deemed to waive any objections and to accept the general terms of the settlement applicable to Foreign Claimants, and

(ii) will have all rights and benefits accorded to Foreign Claimants, including the right to opt out after the court determines the projected amounts payable to Foreign Claimants under the Disease Compensation Schedule. If an opting-in Foreign Claimant should later elect such opt-out right, the Settling Defendants will be precluded from asserting in a defense based on a statute of limitations, statute of repose, or similar proscription the period of time from January 24, 1992, to the date that is 30 days after such person elects to opt-out of the class.

(3) breast-implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not represented by counsel in such settlement and the settlement involved a payment of less than $15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by a Settling Defendant's fraud;

(4) breast-implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant on a breast-implant claim or, after a trial on the merits, shall have had a final judgment entered

against them on a breast-implant claim in favor of a Settling Defendant;

(5) breast-implant recipients who (during the "First Opt Out" period) elect to exclude themselves from the Settlement Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994, or whose Exclusion Form, though received or postmarked after that date, is accepted by the Court as timely; and

(6) any person or entity described in paragraph 2(a)(3) whose status as a class member depends on class membership of a recipient excluded under paragraphs 2(b)(1) through 2(b)(5).

(c) As used in this Order and Judgment, the terms "Settling Defendants" and "Released Parties" mean those persons and entities listed or described in Schedules A and B to the Settlement Notice.

(d) A list of persons excluding themselves from the class will, in order to protect privacy interests to the extent possible, be maintained under seal by the court, with the identity of such persons subject to disclosure only to the extent necessary to protect the rights of the various parties (such as to determine whether a person is precluded from instituting or maintaining some other action).

3. Except as otherwise provided in the terms of settlement as approved by the court:

(a) the Settling Defendants and Released Parties are forever released from any and all claims which any member of the class had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(b) each member of the class is barred and permanently enjoined from instituting, asserting, or prosecuting against any of the Settling Defendants or Released Parties in any pending or future action in any federal or state court in this country, or in any court or tribunal in any other country, any and all claims which such individual had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(c) other persons and entities, not parties to the settlement agreement, against whom members of the class may assert claims for breast-implant related injuries or death are barred from making claims for contribution or indemnification against the Settling Defendants and Released Parties to the extent described in the accompanying Opinion, but are not precluded from asserting any rights to set-off, credit, or reduction that may be allowed under applicable state law; and

(d) other persons and entities, not parties to the settlement agreement, who may have claims for subrogation or reimbursement arising from payment or medical expenses or providing medical services to class members, are barred from making such claims against the Settling Defendants and Released Parties, but are not by this judgment precluded from subsequently attempting to institute or pursue such claims against the settlement fund or class members.

4. Costs are taxed against the settlement funds paid by the defendant.

5. Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs that this judgment, upon filing in CV 94-P-11558-S, be deemed as a final judgment with respect to all claims by members of the class against the defendants herein with respect to breast-implant related injuries or death.

6. Without deferring or delaying the finality of this order and judgment, this court retains exclusive, general, and continuing jurisdiction as needed or appropriate in order to administer, supervise, implement, interpret, or enforce the settlement, including the investment, conservation, protection, allocation, and distribution of the settlement funds.

This the lst day of September, 1994.

/s/ Samuel C. Pointer, Jr.
Samuel C. Pointer, Jr.
United States District Judge

THE NUREMBERG CODE OF ETHICS IN MEDICAL RESEARCH

(1) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be so conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps in those experiments where the experimental physicians also serve as subjects.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he

has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.